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The Group-Based Lifestyle-Integrated Functional Exercise Intervention for Older Adults: Theory- and Evidence Based Intervention Development and Evaluation From a Health Behavior Change Perspective

presented by
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Table of Contents

Abstract

The promotion of healthy aging becomes increasingly important against the background of a growing aging population around the world. The aging process is associated with a loss of physical function and an increased prevalence of falls, which can be effectively prevented by multi-component physical activity such as balance and strength training. However, older adults rarely meet the recommended amount of physical activity or oftentimes withdraw shortly after engagement in interventions.

The Lifestyle-integrated Functional Exercise (LiFE) intervention provides an innovative, habit-based approach to fall prevention and physical activity promotion in older adults by linking functional balance and strength activities to daily routines. This dissertation project is embedded in the LiFE-is-LiFE trial, a randomized non-inferiority trial with the aim to make LiFE suitable for large-scale implementation by developing and testing a group-based LiFE (gLiFE) format.

The aims of the presented work are to enrich the LiFE-is-LiFE project and differentiate it from the health behavior change perspective. gLiFE was developed and evaluated alongside the MRC guidelines for the development and evaluation of complex interventions with a focus on psychological determinants of behavior change. In the development process of gLiFE, empirically established health psychological theories such as the health action process approach (HAPA), the self-determination theory, and habit formation theory as well as the behavior change technique (BCT) taxonomy were applied. To better understand how gLiFE promotes physical activity and prevents falls, gLiFE was evaluated in comparison to LiFE with regard to multiple outcomes, such as effectiveness (e.g., activity-adjusted falls), the participants' perceptions, and changes in psychological determinants of health behavior change (e.g., motivational and volitional constructs or habit strength).

Community-dwelling older adults aged 70 years and older at risk of falling were eligible for participation in the LiFE-is-LiFE trial. LiFE and gLiFE were both delivered in seven intervention sessions over the course of 11 weeks, followed by two booster phone calls. The baseline sample comprised *N* = 309 individuals who were 78.8 (range 70-94) years old on average, with the majority of participants being female (73.5%). Follow-up assessments took place 6 and 12 months after intervention start.

This dissertation project includes six publications which are based on data from the LiFE-is-LiFE trial. The first publication was preparatory research to examine the relationship between theory-based psychological determinants derived from the HAPA and self-determination theory with older adults' sensor-measured daily walking duration as a specific marker for physical function. Findings indicate that intrinsic motivation, but not HAPA-based social-cognitive determinants were related to older adults' walking duration.

The second publication presented the conceptual gLiFE framework and its initial feasibility testing. My contribution was the modification and extension of the original conceptual LiFE model regarding behavior change theory. The development process resulted in a gLiFE trainer's manual. The results of the initial feasibility testing suggest that gLiFE is feasible, accepted by the target group, and is associated with positive changes in psychological determinants of behavior change such as action and coping planning or habit strength.

In the third publication, the evaluation of LiFE and gLiFE from the participants' perspective was reported with a focus on acceptability. Results of qualitative analyses based on focus group interviews with a subsample of participants (n = 30) who completed the 6-month follow-up suggest that participants accept gLiFE and LiFE equally. Regarding behavior change, LiFE and gLiFE participants reported successful habit formation.

The latter three publications were based on data from the full sample assessed at 6- and 12-month follow-up. In the fourth publication, the new gLiFE intervention underwent a non-inferiority testing regarding activity-adjusted falls, which revealed inconclusive results. Although gLiFE participants did not show a similar reduction of activity-adjusted falls as LiFE participants, they significantly increased their daily step count compared to LiFE participants.

In the fifth publication, a quantitative evaluation of participants' perspective on LiFE and gLiFE regarding general and more specific contents such as behavior change strategies like action planning was conducted using data from the 6- and 12-month follow-up. Overall, gLiFE participants rated the overall satisfaction, program-specific aspects, and perceived effectiveness as good and stable over time. Compared to the ratings of LiFE participants, only marginal differences arose, e.g., regarding the perceived helpfulness of planning.

In the sixth and final publication, the changes in psychological determinants of behavior change (i.e., self-efficacy, outcome expectancies, risk perception, intention, action planning, coping planning, action control, habit strength, autonomy, competence, relatedness, and intrinsic motivation) through LiFE and gLiFE were reported. Results showed that LiFE and gLiFE mainly induced long-term changes in volitional determinants such as action control. Both LiFE and gLiFE participants still showed above mid-scale levels of habit strength of the LiFE activities at 12-month follow-up.

Taken together, the current work provides evidence for gLiFE to be a valuable theory-based fall prevention and physical activity promotion intervention for older adults aged 70 years and older. The discussion lays out similarities and differences between LiFE and gLiFE. My research suggests implications for research, referring to both the behavior change process and to the delivery of LiFE and gLiFE. Additionally, implications for gLiFE trainers and potential stakeholders are provided. The dissemination of gLiFE has already been initiated, paving the way for a larger number of older adults to be supported in aging healthily and actively.

Abstract (Deutsch)

Die Förderung von gesundem Altern wird vor dem Hintergrund einer weltweit zunehmend alternden Bevölkerung immer wichtiger. Der Alterungsprozess ist mit einem Verlust der körperlichen Funktionsfähigkeit und einer erhöhten Sturzhäufigkeit verbunden, jedoch kann dem durch multimodale körperlicher Aktivität, beispielsweise der Kombination aus Gleichgewichts- und Krafttraining, effektiv vorgebeugt werden. Nur wenige ältere Menschen sind jedoch ausreichend körperlich aktiv oder beenden ihre Teilnahme an Interventionen oft nach kurzer Zeit. Die Lifestyle-integrierte Functional Exercise (LiFE) Intervention bietet einen innovativen, gewohnheitsbasierten Ansatz zur Sturzprävention und Förderung der körperlichen Aktivität älterer Menschen, bei dem funktionelle Gleichgewichts- und Kraftübungen mit täglichen Routinen verknüpft werden. Dieses Dissertationsprojekt ist in die LiFE-is-LiFE-Studie eingebettet, eine randomisierte Nichtunterlegenheitsstudie mit dem Ziel, LiFE durch die Entwicklung und Erprobung eines gruppenbasierten LiFE (gLiFE) für eine großflächige Implementierung nutzbar zu machen.

Die Ziele der vorgestellten Arbeit bestanden darin, das LiFE-is-LiFE-Projekt aus der Perspektive der Gesundheitsverhaltensänderung zu bereichern und auszudifferenzieren. gLiFE wurde anhand der MRC-Richtlinien zur Entwicklung und Evaluation komplexer Interventionen mit Fokus auf psychologische Determinanten der Verhaltensänderung entwickelt und evaluiert. Im Entwicklungsprozess von gLiFE wurden empirisch fundierte gesundheitspsychologische Theorien wie das Prozessmodell gesundheitlichen Handelns (Health Action Process Approach; HAPA), die Selbstbestimmungstheorie, die Theorie zur Gewohnheitsbildung sowie die Taxonomie der Verhaltensänderungstechniken (Behavior Change Techniques; BCTs) angewendet. Um besser zu verstehen, wie gLiFE körperliche Aktivität fördert und Stürze verhindert, wurde gLiFE im Vergleich zu LiFE hinsichtlich mehrerer Endpunkte wie Effektivität (z.B. aktivitätsadjustierte Stürze), die Wahrnehmung der TeilnehmerInnen und Veränderungen in psychologischen Determinanten der Gesundheitsverhaltensänderungen, zum Beispiel Motivations- und Volitionskonstrukte oder Gewohnheitsstärke, evaluiert.

Zuhause lebende ältere Menschen ab 70 Jahren mit Sturzrisiko konnten an der LiFE-is-LiFE-Studie teilnehmen. LiFE und gLiFE wurden jeweils in sieben Interventionssitzungen im Laufe von elf Wochen und zwei darauffolgenden Telefonanrufen vermittelt. Die Baselinestichprobe umfasste N = 309 Personen, die im Durchschnitt 78,8 Jahre alt waren (Spannweite 70–94 Jahre), wobei die Mehrheit der TeilnehmerInnen weiblich war (73,5 %). Die Nachbeobachtungen fanden sechs und zwölf Monate nach Interventionsbeginn statt.

Dieses Dissertationsprojekt umfasst sechs Publikationen, die auf Daten der LiFE-is-LiFE-Studie basieren. Die erste Veröffentlichung war eine vorbereitende Untersuchung zur Beziehung zwischen theoriebasierten psychologischen Determinanten, die aus dem HAPA und der

Selbstbestimmungstheorie abgeleitet wurden, und der sensor-gemessenen, täglichen Gehdauer älterer Menschen als spezifischem Marker für die körperliche Funktionsfähigkeit. Die Ergebnisse weisen darauf hin, dass intrinsische Motivation, aber nicht HAPA-basierte, sozialkognitive Determinanten mit der Gehdauer älterer Menschen zusammenhängen.

Die zweite Veröffentlichung stellt das gLiFE-Konzept und seine erste Machbarkeitsstudie vor. Mein Beitrag war die Modifikation und Erweiterung des ursprünglichen konzeptionellen LiFE-Modells in Bezug auf die Verhaltensänderungstheorie. Der gLiFE Entwicklungsprozess resultierte in einem gLiFE-Trainerhandbuch. Die Ergebnisse der ersten Durchführbarkeitstests deuten darauf hin, dass gLiFE machbar ist, von der Zielgruppe akzeptiert wird und mit positiven Veränderungen in psychologischen Determinanten der Verhaltensänderungen wie Handlungs- und Bewältigungsplanung sowie Gewohnheitsstärke assoziiert ist.

Die dritte Veröffentlichung beinhaltet die Evaluation von gLiFE im Vergleich zu LiFE aus Sicht der TeilnehmerInnen mit Fokus auf der Akzeptanz beider Formate. Die Ergebnisse qualitativer Analysen auf der Grundlage von Fokusgruppeninterviews mit einer Teilstichprobe von Teilnehmern (n = 30), die bereits die 6-Monatsmessung abgeschlossen hatten, deuten darauf hin, dass gLiFE von den TeilnehmerInnen gleichermaßen akzeptiert wurde wie LiFE. In Bezug auf Verhaltensänderungen berichteten LiFE- und gLiFE-TeilnehmerInnen über eine erfolgreiche Gewohnheitsbildung.

Die letzten drei Veröffentlichungen basieren auf den Daten aus der 6- und 12-Monatsmessung der vollständigen Stichprobe. In der vierten Veröffentlichung wurde die neue gLiFE-Intervention einer Nicht-Unterlegenheitsprüfung in Bezug auf aktivitätsadjustierte Stürze unterzogen, die nicht schlüssige Ergebnisse lieferte. Obwohl die gLiFE-TeilnehmerInnen ihre aktivitätsadjustierten Stürze nicht so sehr reduzierten wie die LiFE-TeilnehmerInnen, erhöhten sie ihre tägliche Schrittzahl im Vergleich zu den LiFE-TeilnehmerInnen signifikant.

In der fünften Veröffentlichung wurde eine quantitative Auswertung von LiFE und gLiFE hinsichtlich allgemeiner sowie programmspezifischer Inhalte wie Verhaltensänderungsstrategien, beispielsweise Handlungsplanung, aus Sicht der TeilnehmerInnen unter Verwendung der Daten des 6- und 12-Monats-Follow-up durchgeführt. Insgesamt bewerteten die gLiFE-TeilnehmerInnen die Gesamtzufriedenheit, die programmspezifischen Aspekte und die wahrgenommene Effektivität als gut und stabil über die Zeit. Im Vergleich zu den Bewertungen der LiFE-TeilnehmerInnen ergaben sich nur marginale Unterschiede, z. B. hinsichtlich der empfundenen Nützlichkeit der Planung.

In der sechsten und letzten Veröffentlichung wurden die Auswirkungen von LiFE und gLiFE auf psychologische Determinanten von Verhaltensänderungen (d.h. Selbstwirksamkeit, Handlungsergebniserwartungen, Risikowahrnehmung, Intention, Handlungsplanung, Bewältigungsplanung, Handlungskontrolle, Gewohnheitsstärke, Autonomie, Kompetenz, Verbunden-

heit und intrinsische Motivation) berichtet. Die Ergebnisse zeigten, dass LiFE und gLiFE hauptsächlich langfristige Veränderungen in volitionalen Determinanten wie Handlungskontrolle induzierten. Sowohl die LiFE- als auch die gLiFE-TeilnehmerInnen zeigten bei der Nachbeobachtung nach 12 Monaten immer noch Werte an Gewohnheitsstärke in Bezug auf die LiFE Übungen, die über dem Skalenmittelwert lagen.

Zusammengenommen zeigt die aktuelle Arbeit, dass gLiFE eine wertvolle theoriebasierte Intervention zur Sturzprävention und Förderung der körperlichen Aktivität für ältere Menschen ab 70 Jahren ist. In der Diskussion werden Gemeinsamkeiten und Unterschiede zwischen LiFE und gLiFE gegenübergestellt. Meine Forschung legt Implikationen für die Forschung nahe und bezieht sich dabei sowohl auf den Verhaltensänderungsprozess als auch auf die Vermittlung von LiFE und gLiFE. Darüber hinaus werden Implikationen für gLiFE-TrainerInnen und potenzielle Stakeholder diskutiert. Die Dissemination von gLiFE wurde bereits angestoßen und ebnet damit den Weg um ältere Menschen flächendeckend dabei zu unterstützen, gesund und aktiv zu altern.

List of Publications

Publication I:

Labudek, S., Fleig, L., Jansen, C.-P., Kramer-Gmeiner, F., Nerz, C., Becker, C., Klenk, J., & Schwenk, M. (2021). Applying social cognition models to explain walking duration in older adults: The role of intrinsic motivation. *Journal of Aging and Physical Activity*, *29*(5), 744-752. https://doi.org/10.1123/japa.2020-0296

Publication II:

Kramer, F.*, Labudek, S.*, Jansen, C.-P., Nerz, C., Fleig, L., Clemson, L., Becker, C., & Schwenk, M. (2020). Development of a conceptual framework for a group-based format of the Lifestyle-integrated Functional Exercise (gLiFE) programme and its initial feasibility testing. *Pilot and Feasibility Studies*, 6(1), 6. https://doi.org/10.1186/s40814-019-0539-x

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Publication III:

Reicherzer, L., Kramer-Gmeiner, F., Labudek, S., Jansen, C.-P., Nerz, C., Nystrand, M., Becker, C., Clemson, L., & Schwenk, M. (2021). Group or individual lifestyle-integrated functional exercise (LiFE)? A qualitative analysis of acceptability. *BMC Geriatrics, 21,* 93. https://doi.org/10.1186/s12877-020-01991-0

Publication IV:

Jansen, C.-P., Nerz, C., Labudek, S., Gottschalk, S., Kramer-Gmeiner, F., Klenk, J., Dams, J., König, H.-H., Clemson, L., Becker, C., & Schwenk, M. (2021). Lifestyle-integrated functional exercise to prevent falls and promote physical activity: Results from the LiFE-is-LiFE randomized non-inferiority trial. *International Journal of Behavioral Nutrition and Physical Activity*, *18*(1), 1–12. https://doi.org/10.1186/s12966-021-01190-z

Publication V:

Wolf, M. J., Labudek, S., Endress C., Jansen, C.-P., Nerz, C., Becker, C., Clemson, L., & Schwenk, M. (2022). *Participants' evaluation of the individual and group-based LiFE program: Results from the LiFE-is-LiFE trial.* [Manuscript submitted for publication to *Aging Clinical and Experimental Research*]. Network Aging Research, Heidelberg University.

Publication VI:

Labudek, S., Fleig, L., Jansen, C.-P., Kramer-Gmeiner, F., Nerz, C., Clemson, L., Klenk, J., Becker, C., & Schwenk, M. (2022). *Changes in psychological determinants of behavior change after individual vs. group-based lifestyle-integrated fall prevention: Results from the LiFE-is-LiFE trial.* [Manuscript submitted for publication to *Gerontology*]. Network Aging Research, Heidelberg University.

Introduction and Overview

In the face of an aging population, there is growing scientific and political interest around how to best support individuals in maintaining health in older age. Physical activity, with its beneficial health effects, is regarded as one of the key factors for healthy aging (Daskalopoulou et al., 2017). Physical activity recommendations for older adults include multifactorial training, meaning not only cardiovascular, but also balance and strength training are necessary in order to maintain physical function and prevent falls. Most older adults, however, fall below physical activity recommendations (World Health Organization [WHO], 2020b) or relapse to initial physical inactivity levels shortly after participating in intervention programs (Sansano-Nadal et al., 2019). To ensure healthy aging, alternative approaches that promote long-term maintenance of regular physical activity effectively are needed.

The Lifestyle-integrated Functional Exercise (LiFE) program (Clemson et al., 2012) is such a program. It has already been shown to effectively promote physical activity while simultaneously reducing falls in community-dwelling older adults (≥ 70 years) long-term. LiFE provides a concept to improve physical function and promote physical activity incidentally by integrating functional balance and strength activities into daily routines, i.e., it encourages older adults to form new movement habits towards an activity-enriched everyday life.

By applying behavior change theories and their practical applications to the field of fall prevention and physical activity promotion in fall-prone older adults in the LiFE context, the presented thesis brings together health behavior research and fall prevention research. Both health behavior research and fall prevention research have existed and evolved over decades, but more as parallel strings instead of intertwined and mutually spurring disciplines. In recent years, there have been few examples where fall prevention was enriched by health behavior change research (Arkkukangas et al., 2019, 2020; Pettersson et al., 2021)and vice versa (Fleig, McAllister, et al., 2016; McHugh et al., 2018). However, an interdisciplinary approach yields advantages for both health behavior and fall prevention research. Health behavior research acknowledges the importance of individual health behaviors such as physical activity for the maintenance of health and prevention of diseases. Physical activity is mainly measured in terms of cardiovascular activity, while balance and strength exercises are underrepresented. This is surprising, as balance and strength are essential for the maintenance of physical function, which is associated with independence and quality of life in older age. Fall prevention research, in contrast, is mainly driven by clinical questions such as impact of interventions on fall-associated outcomes. Yet, fall prevention interventions show restricted long-term sustainability and often lack theoretical explanations of how behavioral changes are assumed to be facilitated by these interventions.

A major issue for the current work has been that the behavior change process initiated through LiFE did not get enough attention previously, leaving it unclear how the effects of LiFE unfold and whether habits are actually established trough LiFE. This dissertation project was conducted with the goal of augmenting the original LiFE-is-LiFE trial with the health psychological perspective, which guided the development and evaluation of the group-based LiFE (gLiFE) format, using a theory and evidence-based approach. The presented thesis was mainly driven by two questions: a) How can gLiFE best be delivered for promoting long-term behavior change and habit formation? and b) How does gLiFE work compared to LiFE? This second aspect, considered as the intervention evaluation, exceeds the assessment of clinically relevant outcomes. Thus, this work, according to the current Medical Research Council (MRC) guidance for the development (Craig et al., 2008) and process evaluation (Moore et al., 2015) of complex interventions, also considers psychological outcomes and the participants' perspective as evaluation outcomes.

These questions were examined within the course of the LiFE-is-LiFE (Jansen et al., 2018), a multi-center, single-blinded, randomized, non-inferiority trial conducted within an interdisciplinary team of researchers. The trial was originally set up to examine whether the newly developed group-based LiFE (gLiFE) format is as effective as the resource-intensive one-on-one format (Jansen et al., 2018).

In the gLiFE development process, empirically established health behavior change theories such as the health action process approach (HAPA; Schwarzer, 2008) or theory on habit formation (Gardner & Lally, 2018) were applied to the behavior change process in gLiFE. As preparatory work, the HAPA was applied to the baseline walking duration of the LiFE-is-LiFE participants (chapter 4.1). The behavior change contents of gLiFE were structured along the intervention progress and broken down into lay-appropriate units (see chapter 3.3.1). The mode of delivery was defined and adapted to the behavior change content. All adaptations were recorded in the gLiFE manual, and additional information on behavior change was provided for gLiFE trainers and the interdisciplinary research team. The original LiFE materials were redesigned and created according to the new behavior change concept, for example by adding space for action planning and action control in the activity planner. The results of the gLiFE development process including the gLiFE concept as well as its initial feasibility testing are reported in chapter 4.2. Participants' opinion on the new gLiFE program with regard to aspects of behavior change was examined via both qualitative and quantitative means. Results of these analyses are reported in chapter 4.3 and chapter 4.5, respectively.

In terms of the hands-on adaptation of the (g)LiFE content and materials, the original LiFE content and gLiFE content was coded by using the behavior change technique (BCT) taxonomy v1 (Michie, Ashford, et al., 2011). This is important for streamlining intervention research and examining the so-called *active ingredients* of behavioral interventions. In order to better

understand the behavior change and habit formation process underlying LiFE and gLiFE, an assessment battery containing the essential theory-based determinants of behavior change was designed and applied throughout the LiFE-is-LiFE trial. The changes in LiFE's and gLiFE's psychological determinants of behavior change are examined and reported in chapter 4.6.

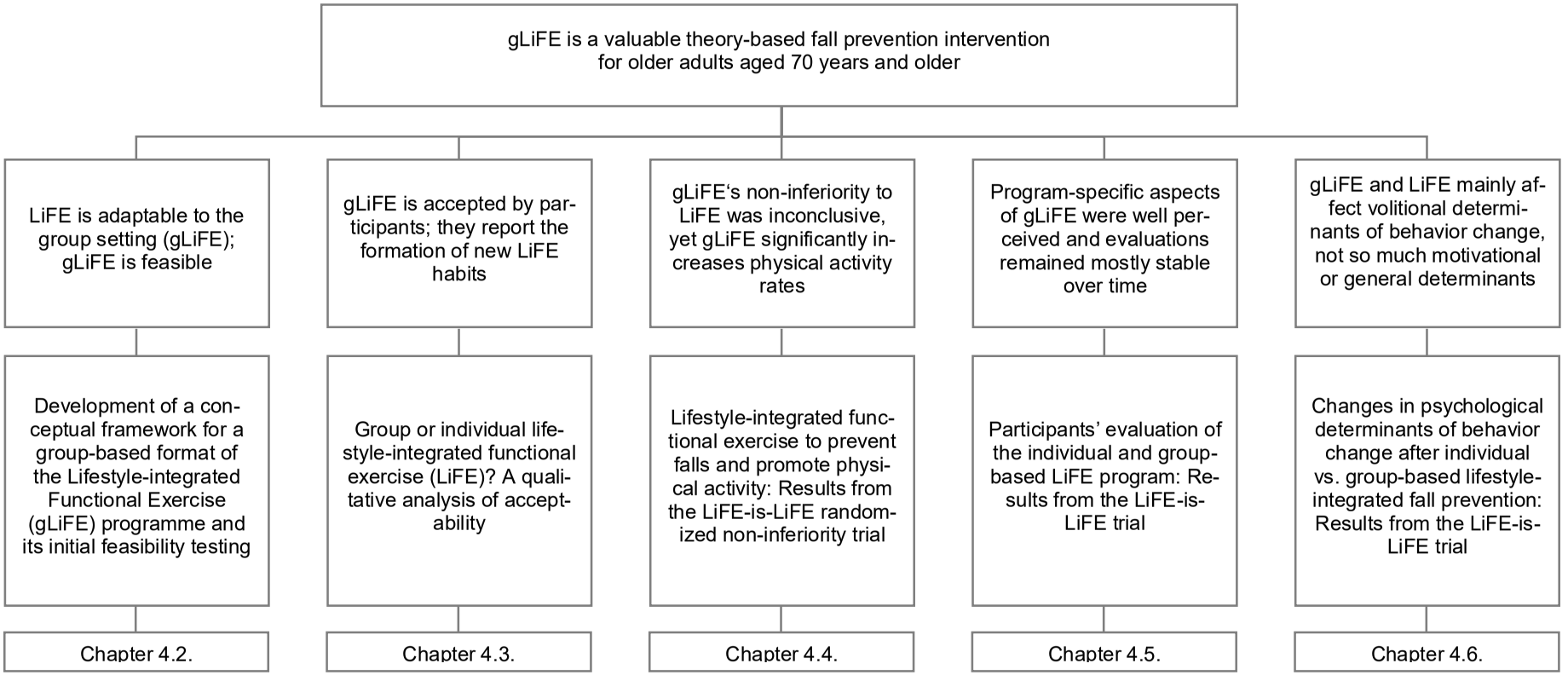
Seeing as the presented thesis is embedded in the umbrella trial, this work shows intersections with the main trial. For example, the question of whether LiFE is effective in preventing falls and promoting physical activity is detrimental to examining the underlying processes of behavior change. That is, if the intervention had not been effective to a clinically important extent, examining how the intervention works would have been somewhat void. This is why the results of the non-inferiority testing of gLiFE compared to LiFE regarding activity-adjusted falls is reported in chapter 4.4.

Apart from the scientific output this work created, it also proves the fruitfulness of interdisciplinary work. I acquired knowledge about fall prevention and physical activity in older adults and got trained to be a LiFE and gLiFE trainer myself. In turn, I could convey important behavior change theories and techniques to my colleagues, and I am proud that my colleagues are able to apply those theories and techniques themselves and that the behavior change part is now strongly ingrained in the gLiFE concept.

All in all, this dissertation project builds on the foundation of six papers that are already published or submitted to international, peer-reviewed journals, and it shows that gLiFE is a valuable theory-based fall prevention intervention for older adults aged 70 years and older (Figure 1). However, these are just the "neutral" facts. What the elderly learn in the LiFE program goes well beyond how to correctly perform the LiFE exercises. They learn how they can pursue an active lifestyle and how they can reduce their risk of falling including fatal consequences. This could, on a larger scale, contribute to an increased quality of life and might help older adults to age healthily.

Figure 1

gLiFE-Related Papers and Key Message of Dissertation



1. Theoretical Background

This first chapter includes the central evidence-based and theoretical concepts this dissertation project is grounded on. Starting from the rationale of promoting healthy aging in older adults, it will be explained why physical activity promotion is key for healthy aging and how state-of-the-art fall prevention research promotes physical activity. These topics will be introduced and explained in order to embed the rationale for the LiFE-is-LiFE trial and the current work properly. Furthermore, the theoretical frameworks for health behavior change and behavioral maintenance will be described, alongside the assumptions and strategies of health behavior interventions.

1.1. Healthy Aging in the Face of Demographic Change

1.1.1. The aging society

Demographic changes impose growing challenges to societies and their health care systems all over the world. Globally, the amount and proportion of older individuals is increasing. The cohort of individuals aged 65 years and older, which made up 9% of the population in 2019, is the fastest growing of all cohorts. It is expected that, by 2050, the proportion of individuals aged 65 years and older will more than double (United Nations, 2019). Numbers are even higher in Europe. The proportion of individuals aged 65 years and older was 20.6% in 2020, and it is expected to be around 30% by 2050 (eurostat, 2021). The main drivers for societal aging are prolonged life expectancies and decreased fertility rates (Harper, 2014). An additional factor is that the so-called *baby boomers*, i.e., an exceptionally large group of individuals born from 1945 to 1964, are now transitioning to older age and retirement.

Although higher chronological age is not necessarily related to a decreased health status (Lloyd-Sherlock et al., 2012), overall, multimorbidity increases with higher age (Palladino et al., 2016). With higher age, the risk for age-related degenerative diseases such as cancer, cardiovascular disorders or neurodegenerative diseases (Gensous et al., 2017; D. Wahl et al., 2019), and multimorbidity increases (Santoni et al., 2015). As a result, the growing number of older adults will increase global health care costs (Lehnert & König, 2012; Palladino et al., 2016). Impaired health and chronic conditions in older age do not only burden the health care system but can also lead to a continuous decrease in quality of life of individuals (Alcañiz & Solé-Auró, 2018; Schmitt, 2008). Supporting older adults in maintaining their health with effective strategies will therefore gain importance in the coming decades (Dipietro et al., 2019; Garatachea et al., 2015). Understanding which processes drive aging and, more importantly *healthy aging*, may help to effectively design and promote health campaigns for older adults. The current work presents advancements of the LiFE intervention, a fall prevention and physical activity promotion intervention with the goal of promoting healthy aging.

1.1.2. Aging and healthy aging

To describe the aging process, Izquierdo et al. (2021) recently stated that "The human aging process is universal, ubiquitous and inevitable" (p. 824). In other words, aging is a life-long, multifactorial and non-linear process which takes place on biological, psychological, social, and societal levels (Rowe & Kahn, 1997). From a biological perspective, aging is defined as the gradual increase of molecular and cellular damage (Steves et al., 2012). Gradually, this accumulated damage leads to a decrease in the capability of individuals for optimal functioning and increases the risk for diseases, ultimately leading to death (WHO, 2015). Due to the complex interplay between genetic and environmental risk factors and compensatory mechanisms, heterogeneity between individuals increases with higher age (Ferrucci & Kuchel, 2021; Nguyen et al., 2021). For example, differences occur because of the high variability by which cellular damage can occur and biological mechanisms operate to repair it (Ferrucci et al., 2020). Additionally, societal factors and personal experiences shape how (fast) individuals age and how they might compensate potential losses (Wahl & Heyl, 2015). Therefore, individuals with the same chronological age can differ immensely in their needs, capabilities, and their health status, both mentally and physically.

But when is an individual considered old? Chronological age, although it may not be adequate to compare individuals (Ehni & Wahl, 2020), is often used to define cut-offs for political decisions (e.g., retirement), health behavior recommendations (WHO, 2010), and study inclusion criteria (Menichetti et al., 2016). For example, in the WHO guidelines for physical activity, older adults are defined as individuals aged 65 years and over (WHO, 2010). With regard to falls, which are a major health risk factor for older adults, fall incidence rates are often indicated for older adults aged 65 and over (G. Bergen et al., 2016; Rapp et al., 2014). Therefore, older adults will henceforth also be referred to as individuals aged 65 years and older.

The concepts of *successful aging* and *healthy aging* arose to challenge the long-existing assumption that aging inevitably comes with loss and diseases. Successful aging was originally defined as a low probability of disability or disease, along with high physical and cognitive functioning and active engagement with life (Rowe & Kahn, 1997). This presumes that individual lifestyle choices can help individuals prevent diseases by shaping their lifestyle choices in a positive manner.

A related but more inclusive concept is healthy aging, which is defined as "the process of developing and maintaining the functional ability that enables well-being in older age" (WHO, 2015, p.28). *Functional ability* here refers to individuals' physiological and psychological capabilities to meet their own basic needs, navigate through their environment and interact with their social surroundings. By focusing on the functional ability, the concept of healthy aging does not neglect the onset of diseases but rather strengthens the view that living a fulfilled life

is possible, and it concentrates on what older individuals can do even in the face of potential diseases.

To date, strategies on how to foster healthy aging are on the rise. The United Nations announced the *decade of healthy aging* (2021-2030), in which global action toward better care for and involvement of older adults are a focal point (WHO, 2020a). The goal is to improve older adults' individual health trajectories by ensuring high-quality, evidence-based health interventions. Since older adults are assumed to be the most heterogeneous group of all, tailored approaches towards older adults' needs and capabilities are urgently needed to promote healthy aging. This could be implemented through, for example, lifestyle-integrated formats such as LiFE, where older adults can find their own individual training schedule.

1.1.3. Associations between physical function, healthy aging, and falls

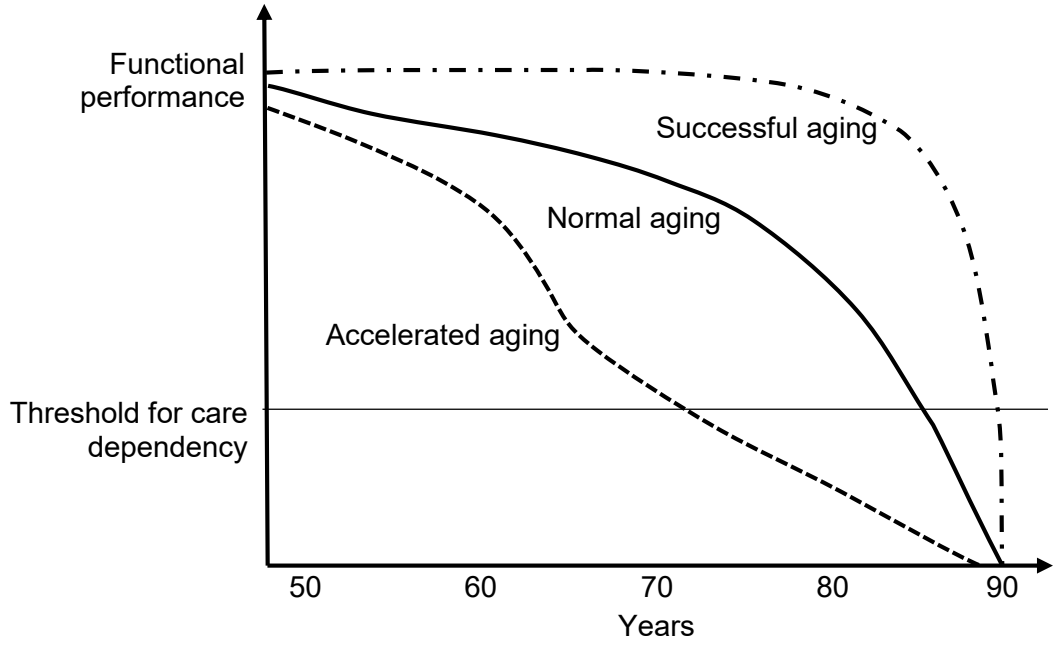
Physical function or capacity plays a key role in healthy aging (Dipietro et al., 2019). Physical function refers to the physical potential of an individual to move their own body, and it builds the foundation to master daily activities and get socially involved (Painter et al., 1999). The basic motor skills which physical function consists of are endurance, balance, strength, speed, agility, and coordination (Meinel & Schnabel, 2007). Many activities of daily living such as grocery shopping, housework and gardening, or personal hygiene mainly involve endurance, balance, and strength. Since higher age is associated with a loss of cardiovascular, balance, and musculoskeletal capacity, older adults often experience a lower physical function and thereby impairments in pursuing their daily tasks (Manini & Pahor, 2008). In line with that, a loss of physical function has shown to be associated with the loss of independence and an increased need for care (Dipietro et al., 2019; Paterson & Warburton, 2010). Different trajectories have been defined on how physical function decreases with increasing age (Jonkman et al., 2018; McPhee et al., 2016; WHO, 2015). In the optimal case (*successful aging*), physical function is maintained on a high level until high age, and then it rapidly declines, leading to death (Figure 2). Individuals who age "normally" would experience a steady decline of physical function with increasing age, falling below the care dependency threshold at one point, which is maintained until death. An example of a worst case would be that of an older adult quickly losing their independence and remaining under the threshold for care dependency over decades (*accelerated aging*). However, research suggests that these trajectories can be altered by explicitly promoting physical function (Liu et al., 2014; McPhee et al., 2016).

On a physical level, poor physical function increases the risk of falling (Masud & Morris, 2001; Tinetti et al., 1988). Studies suggest that around one in three older adults aged 65 years and older falls each year (G. Bergen et al., 2016; Rapp et al., 2014). Falls are ranked among the top reasons for accidents in older populations (Robert Koch-Institut, 2015), and 23-40% of injury-related deaths result from falls. This indicates that falls have a large societal impact due

to the induced costs for the health care system (WHO, 2015). More importantly, falls can have severe consequences for the individual, such as decreased activity levels, fractures, loss of independence, increased mortality, and increased fear of falling (Campbell et al., 1990; Pereira et al., 2008). As a result, older adults may avoid physical activity (Yardley & Smith, 2002), which can create a vicious cycle of falls, decreased physical function and physical inactivity (Jefferis et al., 2014). To counteract the loss of physical function and increased fall risk, effective means to preserve physical function and prevent falls are seriously needed. Ideally, intervention programs are developed with a focus on large-scale implementation, providing fall prevention and physical activity promotion to as many individuals as possible. These interventions should, in turn, be evaluated for their ability to promote physical function and physical activity as well as prevent falls, as it is done in the current work.

Figure 2

Theoretical Trajectories of Aging



Note: This graph was modified on the basis of Jonkman et al. (2018)

1.1.4. Chapter summary

In summary, the aging process is associated with a loss of physical function, which has detrimental effects on both the individual and societal level. Hence, in the face of demographic changes, the promotion of healthy aging through effective promotion of physical function and fall prevention becomes increasingly important. The presented thesis is grounded on the LiFE

intervention, which has already been shown to be effective in preventing falls and promoting physical activity in fall-prone older adults (see chapter 1.5.2).

1.2. Physical Activity and Fall Prevention in Older Adults

Physical activity is defined as any movement caused by the musculoskeletal system with body energy (WHO, 2010). Since it is a complex and multifactorial behavior, physical activity can be described by frequency, intensity, and duration in its essence (Ainsworth et al., 2015). Physical activity can be both movements executed during daily routines (e.g., housekeeping, gardening) or leisure time (e.g., going for a walk), and exercise, which is restricted to more deliberate or structured types of physical activity (Caspersen et al., 1985). The following sections will examine the physical activity recommendations for older adults, the benefits of physical activity in older age, and older adults' preferences for physical activity. Furthermore, an overview of existing physical activity and fall prevention interventions will be given, alongside a presentation of their challenges and shortcomings.

1.2.1. Benefits of physical activity in older age

Due to the extensiveness of positive health effects of physical activity, the New York Times headlined "Closest thing to a Wonder Drug? Try Exercise" (Carroll, 2016). Indeed, over 60 years of research have resulted in an abundance of studies on the positive health effects of regular physical activity across the lifespan. For example, findings from systematic reviews show that physical activity can have beneficial effects that slow the onset of non-communicable diseases like type 2 diabetes or obesity (Reiner et al., 2013), that physical activity is significantly associated with healthy aging (Daskalopoulou et al., 2017), and that physical activity can decrease mortality risk by up to 67% (Ramakrishnan et al., 2021). Older adults can even decrease their mortality risk by taking up low doses of physical activity (Hupin et al., 2015; Klenk et al., 2016; Stessman et al., 2009). Findings from longitudinal studies suggest that increased physical activity in terms of walking, agility, and endurance can improve physical independence and reduce major mobility disability (Pereira et al., 2016; E. D. Williams et al., 2014). Additionally, regular physical activity is related to a decreased risk of fall-related injuries (Dipietro et al., 2019). Aside from the positive physiological effects, physical activity also has shown positive effects on mental health, including cognitive decline, dementia, Alzheimer's disease and depression, and quality of life (Cunningham et al., 2020).

1.2.2. The relationship between physical activity and falls

An important fact that cannot be ignored when aiming to promote physical activity in older age is, however, that higher physical activity rates can be associated with higher fall rates (Gregg et al., 2000; Mertz et al., 2010). Evidence suggests that older adults with poor physical function experience more falls when increasing their physical activity levels (Jefferis et al., 2015; Mertz

et al., 2010). In addition to the physiological impairments which might cause the increased fall rate, fall risk exposure is higher for older adults when being active compared to being sedentary (Gregg et al., 2000). Against this background, multifactorial training such as including balance and strength training into movement regimes for older adults is even more important (Sherrington et al., 2019).

1.2.3. Physical activity recommendations for older adults

The recommendations for physical activity in older adults have changed in the last decade. In 2010, the WHO recommend older adults aged 65 years and older to engage in at least 150 minutes of moderate or 75 minutes of vigorous physical activity per week, with minimum bouts of 10 minutes (WHO, 2010). Newer recommendations also stress the health benefits of shorter bouts, add so-called incidental physical activity, and acknowledge the fact that the *relative intensity* of physical activity might be higher for older adults (Piercy et al., 2018; Stamatakis et al., 2019). Furthermore, recommendations now highlight that “every more counts”, suggesting that every increase of physical activity is beneficial for health (Piercy et al., 2018).

Additionally, older adults are explicitly recommended to engage in multicomponent physical activity involving *functional* balance (twice weekly) and strength training (on three or more days per week) to maintain or improve physical function and prevent falls. Functional exercise refers to any kind of exercise which aims to improve a specific movement (Liu et al., 2014). In the case of older adults who might be at risk of falling, the movements might be similar to or closely related to activities of daily living, such as climbing stairs, rising from a chair, or walking on a narrow path.

1.2.4. Physical activity rates in older adults

Despite the extensive positive effects of physical activity, the majority of older adults all over the world do not meet the recommendations for physical activity. Across different age groups, older adults are the most inactive cohort (Hallal et al., 2012). A European study showed that less than 30% of older adults aged 65 years and older meet the recommended amount of 150 minutes of moderate to vigorous physical activity (Lange & Finger, 2017). Regarding the recommended combination of endurance and strength training, only 17.4% of older adults in Germany meet the recommendations (Finger et al., 2017). There are no recent studies on the engagement of older adults in balance training. However, results from an Australian survey suggest that the prevalence is even lower, around 12.2% (Merom et al., 2012). These low rates of physical activity contributes to a substantial burden of chronic disease and mortality (Keadle et al., 2016). However, individual physical activity and modifiable health behavior has the potential to be altered by effective intervention strategies.

1.2.5. Predictors for older adults' physical activity

The influences on physical activity as a complex health behavior are manifold. To effectively promote physical activity among older adults, understanding the factors that facilitate or impede physical activity is crucial. In general, predictors for physical activity can range from environmental to demographic to social-cognitive predictors, and the associations between physical activity behavior and those factors can be more proximally or rather distally (Giles-Corti et al., 2005).

Studies about the effects of certain environmental factors on physical activity do not seem to be in total agreement. Findings from a systematic review suggest that the built environment (e.g., walkability, neighborhood safety) influences older adults' participation in physical activity (D. W. Barnett et al., 2017), which is in contrast to a large cross-sectional study that found no significant relationship between built environment and physical activity (McKee et al., 2015). Gellert et al. (2015) found that person-related factors might have a stronger influence on older adults' physical activity than environmental factors. However, findings from a study by Fleig, Ashe, et al. (2016) suggest that the built environment might be indirectly associated with older adults' physical activity by first affecting confidence in walking. Another study found that physical health and physical environment were not significantly associated with physical activity and pointed towards the importance of individual, modifiable factors such as time spent sedentary (McKee et al., 2015).

Regarding demographic factors, a longitudinal study over 10 years revealed that higher age and female sex were related to a lower likelihood of engaging in regular physical activity in older age (Smith et al., 2015). This was also found by a systematic review (Koeneman et al., 2011). For marital status, two studies reported contrary results (Koeneman et al., 2011; van Stralen et al., 2009), whereas the review, which also considered study quality, did not find evidence for a relationship between marital status and physical activity in older adults. Other studies suggest that low socio-economic status (SES) is negatively associated with physical activity (I. Barnett et al., 2012; Gray et al., 2016; van Stralen et al., 2009) and physical function (Stringhini et al., 2018).

Many studies also investigated the influence of social-cognitive predictors on physical activity, which are mainly examined via self-report data (Baert et al., 2011; Gellert et al., 2015; Schutzer & Graves, 2004). Here, the factors examined are often referred to as motivators and barriers for physical activity. Evidence suggests that physical function can serve as both an important motivator but also a major barrier for older adults to engage in physical activity (Baert et al., 2011; Gellert et al., 2015). Findings from a large cross-sectional study (N = 1,937 aged 72-93 years) suggest that poor health was considered impeding for physical activity more often by older adults aged 80 years and over compared to younger individuals (Moschny et al., 2011). However, a recent study suggests that *perceived* rather than objective health barriers predicted

older adults' physical activity (Warner et al., 2019). In line with that, studies suggest that positive attitudes towards one's own aging are positively associated with physical activity engagement (Emile et al., 2014; Levy & Myers, 2004).

In the systematic review by Baert et al. (2011), reported barriers were lack of time, lack of motivation, and lack of interest. Indeed, the importance of physical activity motivation for physical activity behavior is assumed to increase with age (Hagger et al., 2002). Gellert et al. (2015) also found evidence that the lack of interest is a barrier for older adults and concluded that interventions might consider that older adults prefer the enjoyment of being physically active itself over cognitive beliefs about the benefits of physical activity (Carstensen et al., 2003; Gellert et al., 2012).

The fact that enjoyment or *intrinsic motivation* might be important for older adults to engage in physical activity is also supported by other studies (Arnautovska, O'Callaghan, et al., 2017; Arnautovska et al., 2019; Ferrand et al., 2014; Lewis et al., 2016; Phoenix & Orr, 2014). Findings from a study in older adults who participated in physical activity programs regularly suggest that individuals who show higher levels of intrinsic motivation while being physically active exercise significantly more compared to individuals who exercise out of conscientiousness or external reasons (Ferrand et al., 2014). Two other studies also provide evidence for the relationship between intrinsic motivation and physical activity (Arnautovska, O'Callaghan, et al., 2017; Arnautovska et al., 2019). Lewis et al. (2016) examined the relationship between enjoyment and self-efficacy and found that when included as single predictors, enjoyment but not self-efficacy predicted older adults' physical activity. However, they also found that the relationship of enjoyment and physical activity was mediated by self-efficacy, suggesting that self-efficacy might result from a broader sense of being motivated (D. M. Williams & Rhodes, 2016). Self-efficacy as a predictor for older adults' physical activity was also identified in the systematic review by Baert et al. (2011), and in other studies (Booth et al., 2000; Kim & Kosma, 2013; S. M. White et al., 2012). Furthermore, findings from different studies provide evidence for the positive effect of social support on physical activity in older age (Baert et al., 2011; Booth et al., 2000; Kim & Kosma, 2013). Findings of another study revealed a synergistic relationship between self-efficacy and social support, suggesting that both social support and self-efficacy might be necessary for older adults to engage in physical activity (Warner et al., 2011).

Aside from motivation, volitional or self-regulatory factors such as planning are assumed to predict physical activity behavior in general (Schwarzer, 2008). Schutzer and Graves (2004) proposed that while self-efficacy might be crucial for the uptake of physical activity, self-regulatory skills help enact behavioral intentions. Yet some studies suggest that planning does not predict older adults' physical activity (Caudroit et al., 2011) and might not be an adequate strategy to promote older adults' physical activity (D. P. French et al., 2014; Warner et al., 2016). Nevertheless, planning is often reported to be applied in physical activity interventions

among older adults (Senkowski et al., 2019), and there are also studies which find planning to be associated with physical activity (Arnautovska, Fleig, et al., 2017; Fleig et al., 2013; Wolff et al., 2016). Ziegelmann et al. (2006) found that planning is effective for the adoption of physical activity in older adults, especially when provided with assistance from interviewers.

Regarding the influence of implicit processes such as habit on older adults' physical activity, studies suggest that habit strength is associated with physical activity. Habit strength could partially explain why prior physical activity is a predictor of later physical activity (van Bree et al., 2015) and intention is not necessary for physical activity engagement in older adults with high levels of habit strength (van Bree et al., 2013).

Overall, setting aside socio-demographic variables like age and sex, there is evidence for psychosocial, modifiable factors to have a positive effect on physical activity. These factors display a potential target for health behavior interventions. In the gLiFE intervention, motivational, volitional, and more general determinants will be addressed.

1.2.6. Interventions for physical activity promotion and fall prevention

There exist a variety of interventions with the goal of promoting older adults' physical activity. As noted in chapter 1.2.3., physical activity guidelines recommend multi-component interventions for older adults, especially for those who experience an increased risk of falling. Very broadly, every subcomponent of physical function (i.e., endurance, strength, balance, speed, agility, and coordination; Meinel & Schnabel, 2007) can be promoted in interventions using different types of physical activity (see Izquierdo et al., 2021 for an overview, p.830). Aside from the type of physical activity promoted in an intervention, there are many other criteria that can vary between interventions. For example, as outlined in the template for intervention description and replication (TIDieR) checklist, the intervention provider, format of delivery, dose (i.e., frequency and duration), and the degree of tailoring and modifications can be modified (Hoffmann et al., 2014). Delivery can take place face-to-face, individually or in a group, via telephone, digitally, or in hybrid forms (see Grande et al., 2020). A recent systematic review of meta-analyses reported a variety of settings for physical activity interventions in older adults, for example participants' homes, residential retirement homes, community centers, and health care settings (e.g., hospitals, care homes; Di Lorito et al., 2021). Regarding duration, almost half of the interventions included in this systematic review lasted between 6-12 months, and the largest proportion of studies took place at up to five times a week. More studies included strength and endurance training than balance training and only a few studies (12%) included functional exercise. A recent scoping review on physical activity interventions for older adults found that most interventions were mostly structured exercise programs, with many including a home-based component (Taylor et al., 2021). Common features of structured programs are standardized and repetitive exercises, which are performed several times a week.

An alternative approach is so-called *lifestyle-integrated training*, which considers daily routines as opportunities for exercise (Clemson et al., 2010, 2012; see chapter 1.5.1). A systematic review on the feasibility and effectiveness of lifestyle-integrated training found it to be effective in promoting older adults' motor performance (Weber et al., 2018). Besides strictly structured or solely lifestyle-integrated interventions, there are also programs which combine structured and lifestyle-integrated training (Opdenacker et al., 2008).

The effectiveness of more traditional physical activity interventions in older adults has been examined in a meta-analysis by Chase (2015), showing an effect size of d = .18 (95% CI = 0.10 to 0.26) pre-post intervention compared to a control group, which corresponded to 73 minutes of additional physical activity per week. Regarding intervention characteristics that could influence effectiveness, interventions that used audio-visual material, were delivered via mailed materials and were based on a theoretical basis were more effective, whereas the delivery setting did not influence intervention effectiveness.

Another recent systematic review and meta-analysis focusing on more structured types of physical activity found that physical activity interventions are effective in increasing objectively measured physical activity in community-dwelling older adults short-term (standard mean difference [SMD]: 0.30, 95% confidence interval [CI] : 0.17 to 0.43) and intermediate term (SMD = 0.27, 95% CI:0.06 to 0.49; Grande et al., 2020). Regarding long-term effectiveness, however, the examined interventions where not significantly more effective than no or minimal intervention (SMD = 0.19; 95% CI: −0.03 to 0.41). This finding is supported by results from a systematic review of reviews, which included reviews based on self-report and objective physical activity assessment (Zubala et al., 2017). Furthermore, although the results need to be interpreted with caution due to a lack of quality in original studies, the findings suggest that interventions might induce differential effects depending on the outcome, for example, moderate to vigorous physical activity or steps per day (Grande et al., 2020).

A fourth review focusing on fall prevention programs showed that, with all types of fall prevention interventions of 59 studies taken together, the rate of falls can be reduced by 23% (95% CI: 0.71 to 0.83; 12,981 participants) compared to a control condition (Sherrington et al., 2019). Furthermore, findings suggest that multi-component interventions (i.e., balance and functional exercises plus strength training) are most effective (fall rate reduction; 34%, 95% CI: 0.50 to 0.88; 1,374 participants, 11 studies) compared to other interventions like balance training alone or Tai Chi.

1.2.7. Shortcomings of physical activity and fall prevention interventions

There are three major shortcomings of existing physical activity and fall prevention interventions. First, physical activity or fall prevention interventions for older adults have been found to be low-quality, which presents challenges regarding the examination of effectiveness

(Hopewell et al., 2018). To define intervention content and guide scientific evaluation, researchers have recently suggested using the BCT taxonomy (Michie, Ashford, et al., 2011; see chapter 1.4.1) to describe the content of fall prevention interventions (Hughes et al., 2019). Thus, the BCT taxonomy was used to identify the intervention content of the LiFE intervention program. Furthermore, during the development process of the gLiFE format, those BCTs were revised and specified for gLiFE.

Second, physical activity or fall prevention interventions often lack a theoretical basis of how the underlying mechanisms of behavior change are assumed to induce treatment effects. Interventions lacking a theoretical basis have been considered a general problem in health behavior research (Prestwich et al., 2014). There is some evidence on the use of theoretical concepts in the promotion of older adults' physical activity (Teng et al., 2020; Zubala et al., 2017), but the pathways through which the intervention contents induce treatment effects via tackling the assumed theoretical constructs are rarely examined (Senkowski et al., 2019; see chapter 1.4.4). Thus, the present thesis contains the mapping of the LiFE format in line with empirically established theories of behavior change such as the HAPA (Schwarzer, 2008). Aside from defining how LiFE addresses psychological determinants of behavior change, it was examined whether and to which extent LiFE and gLiFE participants report changes in those psychological determinants.

Third, a well-known problem in existing interventions is that older adults rarely adhere to physical activity or fall prevention interventions (Merom et al., 2012). This is problematic because low adherence rates can threaten the intended treatment effects (Fairhall et al., 2017). Especially long-term adherence has been found to be low in older adults. Findings from clinical trials suggest than after one year, only half the participants still adhered to fall prevention interventions (Nyman & Victor, 2012). Another systematic review and meta-analysis included interventions explicitly set up to promote long-term maintenance of physical activity interventions in community-dwelling older adults (Sansano-Nadal et al., 2019). The results indicate that the small clinical benefit of interventions compared to non-active controls vanishes after 6 months of the intervention cessation, rendering the interventions ineffective after 1 or 2 years. Hughes et al. (2019) conducted a systematic review and meta-analysis on interventions which explicitly promoted older adults' adherence to fall prevention interventions and found that telecommunication and lifestyle-integrated training might promote adherence. Furthermore, they concluded that multifactorial approaches guided by theory and evidence on modifiable factors help to promote adherence. Hence, to combat low adherence rates of older adults, alternative approaches which consider the preferences of older adults for physical activity and fall prevention interventions are seriously needed (Clemson et al., 2010; Simek et al., 2015). Reconsidering the sustainability of fall prevention interventions and applying principles of habit formation as a key driver for behavioral maintenance might be a promising pathway towards better long-

term adherence. Hence, as already considered in the original LiFE concept, principles of habit formation were explicitly strengthened in developing the gLiFE concept. The current work tests whether LiFE and gLiFE are capable of inducing habit formation and whether these changes in habit formation are maintained over time.

1.2.8. Older adults' preferences for physical activity interventions

Regarding features of physical activity interventions, several studies have examined what older adults find appealing and what they dislike about physical activity programs. Involving users is not only considered a current standard for evaluating complex interventions (Moore et al., 2015), but the acceptability of a program and its features might also influence intervention effectiveness (Sekhon et al., 2017).

Highly complex interventions and high costs have been shown to be less attractive for older adults (Baert et al., 2011). In this systematic review, other factors mentioned as barriers to engaging in physical activity programs were time constraints, bad weather, and access and transportation to the exercise facility. In another study, older adults reported to prefer no-cost and home-based training with no need to travel (Franco et al., 2015). A further study provided support for the fact that home-based training is more widely accepted by older adults compared to, for example, group-based training (Yardley et al., 2008). However, a large cross-sectional study found that older adults prefer team-based activities over training alone (Burton et al., 2012). One systematic review found social support and low-intensity training, among others, to be enhancing factors for the uptake of fall prevention activities (Bunn et al., 2008). Yardley et al. (2007) found that the intention to take up balance and strength training to prevent falls is predicted by perceived benefits such as a feeling of acceptance and relatedness of the social surrounding rather than potential threats through omission of strength and balance training. However, one study showed that the likelihood of enrollment was higher when having a history of falls (Kiami et al., 2019), suggesting that older adults' views on fall prevention could differ depending on whether they have experienced a fall or not. A qualitative study on the maintenance of physical activity after participation in an exercise program revealed that older adults found physical autonomy, enjoyment, and social interaction to be motivating (Maula et al., 2019). Furthermore, positive evaluation of the activity and physical benefits, positive feedback, development of behavior considered normal or habitual, and self-efficacy were mentioned as motivators.

Researchers recommend physical activity interventions to be tailored to the individual, i.e., considering risk factors, functional abilities and limitations, and personal preferences (Izquierdo et al., 2021). This recommendation is supported by a qualitative study which suggests that inactive older adults would prefer highly tailored approaches (Costello et al., 2011). Furthermore, interventions are requested to be adjustable regarding the modality, frequency,

duration, and intensity, and they should contain practical solutions to support individuals throughout the behavior change process (Izquierdo et al., 2021). The LiFE program is highly tailorable, and its habit-based nature and lifestyle-integrated approach meets both older adults' preferences and current scientific recommendations.

1.2.9. Chapter summary

In summary, despite the numerous benefits of physical activity on older adults' health, older adults often do not meet the recommended amount of multifactorial physical activity. Besides demographic factors such as sex and age, there are environmental, demographic, and social-cognitive predictors associated with older adults' physical activity levels. Interventions with the goal of promoting physical activity and preventing falls mainly induce short-term effects, leaving it unclear how to sustainably promote older adults' physical activity. When considering the preferences of older adults for physical activity and fall prevention programs, consensus builds around affordable, time-efficient, and tailorable approaches. However, individual preferences around more or less sociable intervention options should also be considered. The LiFE intervention, with its habit-based nature and its lifestyle-integrated approach, forms the basis of this work. It combines many preferable features for physical activity and fall prevention interventions in older adults. So far, not much attention has been paid to the psychological mechanisms beyond LiFE, such as how and if LiFE really evokes long-term adherence and behavior change through habit formation. Examining these health psychological aspects of LiFE and the newly developed gLiFE format forms the core of the presented thesis.

1.3. Theoretical Foundations of Health Behavior Change and Maintenance

Behavior change theory is so far often neglected in fall prevention research. However, considering the psychological processes which mediate the behavior change process and eventually lead to behavioral changes and functional improvements is important for fall prevention as a field of health prevention. This chapter provides an overview over the basic principles of health behavior change and maintenance. After addressing the underlying assumptions of many behavior change theories, the three behavior change theories relevant for this dissertation project, the health action process approach, habit formation theory, and self-determination theory, are explained in detail.

1.3.1. Health behavior theories

In the 21st century, non-communicable diseases became the leading global factor for mortality and the accompanying major disease burden (GBD 2019 Risk Factors Collaborators, 2020). Since maladaptive individual health behaviors such as physical inactivity are a main risk factor for the onset of non-communicable diseases, societal interest in the explanation and prediction of health behaviors has grown ever since. Research on health behavior change arose from

the field of social psychology in the 1950s, where it centered on psychological predictors of behavior in social environments, which formed the foundation of many contemporary behavior change theories.

Theoretical models on behavior change make assumptions about how individual, social, and contextual factors promote behavioral changes (Glanz & Bishop, 2010; Kwasnicka et al., 2016; Michie et al., 2008). However, behavioral theories not only entail relevant determinants for behavior change, but also define the relationships between those factors and the health behavior, and they have provided guidance for developing health behavior interventions. There are several criteria which a theory should fulfill (see Prochaska et al., 2008). For example, health behavior theory should be parsimonious, but also make the best possible assumptions about one or even several health behaviors. Many behavioral theories are continuous prediction models and can be displayed with path diagrams, showing direct and indirect influences of one determinant on another, and ultimately on behavior. The assumption of continuous prediction models is that higher levels of one determinant (e.g., intention) lead to higher levels of another determinant (e.g., behavior). Unlike continuous prediction models, stage models assume that individuals progress through qualitatively distinct stages until the final stage, which optimally represents behavioral maintenance (Lippke & Ziegelmann, 2008).

1.3.2. The health action process approach (HAPA)

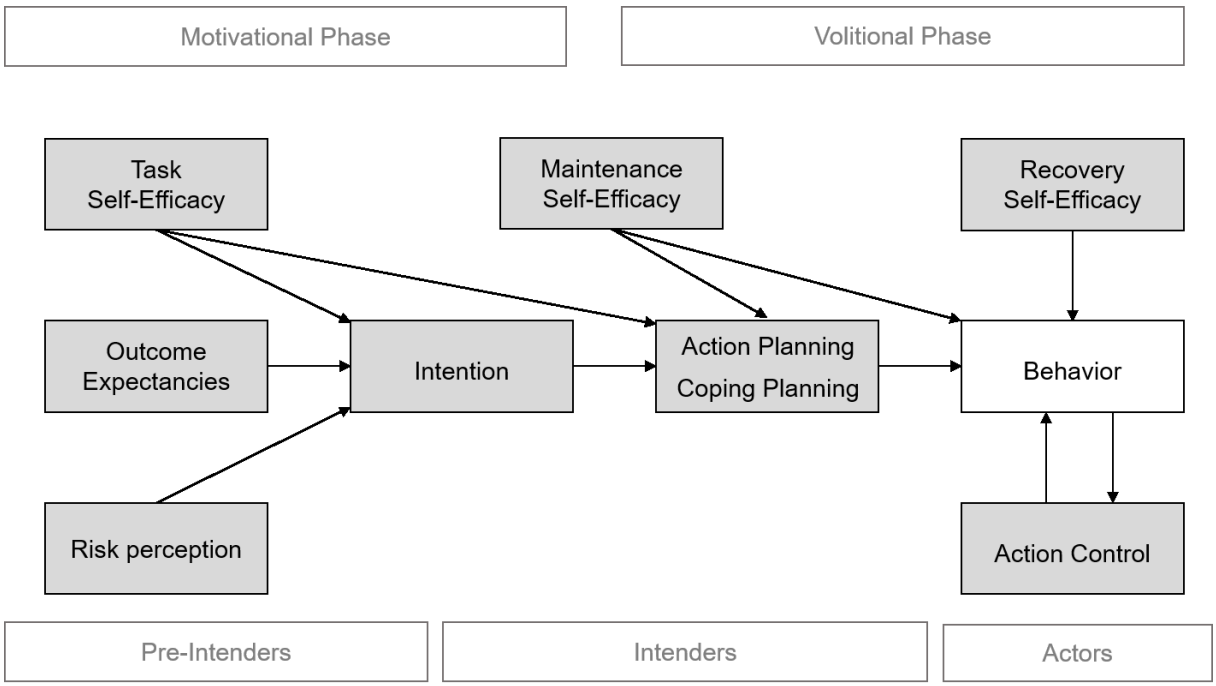
One of the most comprehensive behavior change theories is the health action process approach (HAPA; Schwarzer, 2008), which is an open architecture model designed to be tested in different contexts with different health behaviors. The HAPA combines assumptions of continuous prediction models and stage models by defining both a path model and underlying stages individuals could pass through during a behavior change process. The core assumption of the HAPA is that higher levels of intention induce behavioral changes via volitional determinants such as action planning and coping planning (Figure 3). Additionally, the HAPA accounts for different psychological determinants that have differential impacts on behavior depending on the different stages of behavior change (Schwarzer & Hamilton, 2020), as already proposed in the transtheoretical model of behavior change (Prochaska & DiClemente, 1983) or the Rubicon model (Heckhausen, 1987). Individuals are categorized as being *pre-intenders*, *intenders*, or *actors*, and the behavior change process is divided into a *motivational* and a *volitional* phase. Throughout all stages, self-efficacy in its stage-specific forms is assumed to facilitate the behavior change process.

The development of the HAPA was influenced by the theory of reasoned action (Fishbein & Ajzen, 1975), social-cognitive theory (Bandura, 1977, 2004), and the theory of planned behavior (Ajzen, 1991), containing self-efficacy and intention as their key concepts, respectively. The

HAPA extends these former models by acknowledging the fact that individuals are often motivated to engage in a certain health behavior, but do not act upon their intentions (Abraham & Sheeran, 2000; Orbell & Sheeran, 1998). The so-called intention-behavior gap (Sheeran, 2002) is bridged by adding post-intentional, self-regulatory mechanisms like action and coping planning that form the volitional phase and help to translate intention into action.

Figure 3

The Health Action Process Approach (Schwarzer, 2008)



Note. The grey boxes contain the relevant HAPA determinants for the current work. Exemplary items used in the presented thesis are reported in Table 3.

In the motivational phase, task self-efficacy, outcome expectancies, and risk perception help pre-intenders to form a motivation for changing a certain health behavior, for example engaging in physical activity more regularly. Perceived self-efficacy is defined as the belief in one's own capability to master a specific task, e.g., to engage in regular fall prevention exercise. Self-efficacy is not only present in the motivational stage, but also is assumed to support later stages of the behavior change process: maintenance self-efficacy refers to tasks which appear in the volitional stage (e.g., having optimistic beliefs to keep engaging in regular physical activity despite occurring challenges) and recovery self-efficacy refers to the belief in one's own capability to recover from setbacks or lapses during behavioral maintenance (Scholz et al., 2005). Outcome expectancies, i.e., perceived benefits or disadvantages resulting from engaging in a certain health behavior, are perceived to foster intention in cases where the benefits outweigh the disadvantages. Individuals at risk of falling might for example be motivated by

the fact that fall prevention exercises could improve their safety, if they experience the training not to be too hazardous. The last predictor of intention, risk perception towards the perceived severity of a health condition which might result by engaging in or refraining from a certain health behavior, is assumed to induce higher levels of intention as well.

Once the intention is set, individuals become intenders and volitional strategies such as action planning and coping planning are assumed to translate intention into behavior. Action planning refers to making detailed plans on when, where, and how to engage in a certain health behavior. These specifications serve as cues which are assumed to trigger behavioral execution and serve as self-regulatory strategy by helping to direct attention and regulate negative emotions (Schwarzer & Hamilton, 2020). Action planning can, for example, be performed via making detailed *if-then plans* (i.e., implementation intentions; Gollwitzer, 1999), which connect a situational cue with the target behavior. Coping planning, in contrast, is proposed to shield good intentions from arising challenges. For example, going on holiday might threaten the physical activity routines, and anticipated planning of how to engage in physical activity in advance could compensate for potential lapses. The third self-regulatory factor, action control, entails self-monitoring, awareness of standards, and self-regulatory effort which can happen during or after behavioral enactment (Schwarzer & Hamilton, 2020; Sniehotta et al., 2005).

Studies have applied the HAPA to many different health contexts (Bierbauer et al., 2017; Duan et al., 2017; Schwarzer et al., 2007), such as dietary behavior (Hankonen et al., 2014; Steca et al., 2015), smoking cessation (Ochsner et al., 2014), medication adherence (Presseau et al., 2017) and physical activity (Barg et al., 2012; Fleig et al., 2013; Ziegelmann et al., 2006). A meta-analysis including 95 studies provided evidence supporting the overall structure of the HAPA, i.e., small- to medium-sized effects from intention, self-efficacy, and planning on behavior, and the importance of self-efficacy in both the motivational and volitional phase (Zhang et al., 2019). In contrast, some proposed factors, such as risk perception, seem to play a minor role or may be dependent on other factors such as the behavior of interest (Zhang et al., 2019). Only a few studies exist on the application of the HAPA to older adults' physical activity (Bierbauer et al., 2017; Caudroit et al., 2011; Renner et al., 2007). However, the findings suggest that the HAPA is applicable to older adults' physical activity.

Although the HAPA has provided substantial theoretical advances in the field of health behavior change and finds vast empirical support, there are two major shortcomings of the HAPA which are relevant for this dissertation project. First, in the HAPA, motivational quantity is reflected with intentions, but motivational quality is not. In HAPA-based questionnaires, individuals need to rate items like "I intend to engage in regular physical activity" on a Likert-scale (e.g., 1 = *not at all true* to 4 = *exactly true*; see Schwarzer, 2008). Such questions assess *how much* effort individuals are willing to invest to change their behavior. However, intention quality, i.e., *why* individuals engage in physical activity behavior, especially positive emotions or the

fulfillment of personal values, have been found to be a driver for behavior change (Thøgersen-Ntoumani et al., 2016) and behavioral maintenance (Teixeira et al., 2012), including in older adults (Ferrand et al., 2014, see chapter 1.2.5). Self-determination theory (Deci & Ryan, 2000; R. M. Ryan & Deci, 2000) has been used widely to describe and explain different motivational qualities, for example, controlled vs. autonomous types of motivation (see chapter 1.3.3).

Furthermore, similar to the theory of planned behavior, the HAPA focuses on deliberate and cognitive processes and neglects the influence of automatic processes such as habits for behavioral guidance (Sheeran et al., 2013; Sniehotta et al., 2014; see also Arnautovska, 2017). However, habits have been proposed to be a key factor for behavioral maintenance (Kwasnicka et al., 2016) and have also been found to influence older adults' physical activity behavior. A study on older adults' physical activity found that habit mediated the relationship between former and later physical activity engagement when accounting for self-efficacy and intention (van Bree et al., 2015).

To account for those theoretical shortcomings, self-determination theory and theoretical advances on the formation and functioning of habits (Gardner & Lally, 2018; Lally & Gardner, 2013; Wood & Neal, 2007), are additionally used and integrated with the HAPA into the theoretical framework for this dissertation to examine and predict older adults' physical activity behavior. Empirically, applying the HAPA to the context of health promotion in older adults can help to better understand the predictors' health-relevant, accelerometry-measured outcomes such as older adults' walking duration. The following displays the theoretical background on self-determined motivation and habits.

1.3.3. Self-determination theory

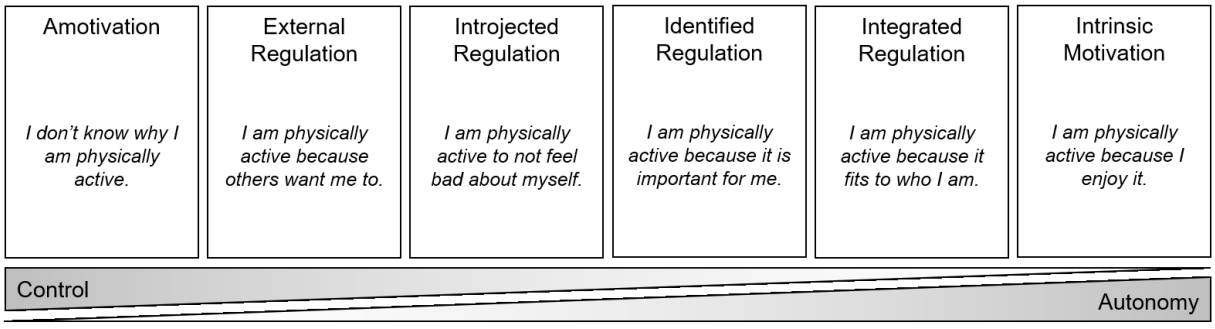
Self-determination theory is an umbrella theory consisting of several mini theories on the interplay between behavior, basic psychological needs, and the source of individual's motivation (R. M. Ryan & Deci, 2000). Regarding basic psychological needs, the self-determination theory assumes three basic needs: autonomy, competence, and relatedness. These lead, when fulfilled, to optimal psychological well-being and functioning (R. M. Ryan & Deci, 2017). A sense of autonomy is proposed to arise when individuals feel able to act upon own choices with ownership, i.e., they intentionally and volitionally engage in a certain action. The need for competence is fulfilled when individuals experience a sense of mastery and control over tasks and behaviors. Relatedness is experienced when individuals feel connected and unconditionally supported (R. M. Ryan & Deci, 2000).

Self-determination theory centers on motivational quality rather than motivational quantity, stressing the reasons *why* individuals engage in a certain behavior. More specifically, motivation is proposed to be a multi-faceted construct with six regulatory styles which are located on

a continuum of self-determination or relative autonomy (R. M. Ryan & Deci, 2017). Self-determination theory broadly distinguishes between amotivation, extrinsic motivation, and intrinsic motivation. Extrinsic motivation can be further sub-divided into more autonomous or more controlled forms of motivation. Integrated and identified motivation stand opposed to less autonomous types of motivation, i.e., introjected, extrinsic motivation or amotivation (Figure 4). More autonomous types of motivation reflect a higher sense of choice, interest, competence, engagement, and enjoyment which translates into the internalization of health as a value and better maintenance of behaviors through health-focused behavioral regulation (Hagger, Hankonen, et al., 2020; R. M. Ryan & Deci, 2017). In contrast, individuals experience more controlled types of motivation when acting upon external demands such as social pressure. Intrinsic motivation as the most autonomous type of motivation is defined to arise whenever a task is interesting and enjoyable by itself without being linked to any external outcomes such as social reward (Deci, 2004). Self-determination theory has been successfully applied to predict health behaviors (Ng et al., 2012) and to deliver health behavior (Ntoumanis et al., 2021). In the context of physical activity, intrinsic motivation means that individuals like and enjoy being physically active (Markland & Tobin, 2004). Ryan et al. (2009) state, however, that most types of physical activity are driven by mixed types of motivation. They propose that “even the most enjoyable sport activities often require periods of extrinsically motivated practice” (p. 111), but more intrinsically motivated activities are more likely to be sustained over time. Trainers are assumed to promote intrinsic motivation by promoting autonomy and competence.

Figure 4

Motivational Continuum on Basis of the Self-Determination Theory



Note. The examples in italics refer to physical activity, respective items are used in the current work. Chapter 4.1 reports the extension of the HAPA by intrinsic motivation.

Physical activity interventions in older adults might profit from focusing on intrinsic motivation. Why intrinsic motivation might be particularly important for older adults’ physical activity can be explained with assistance from the socio-emotional selectivity theory (Carstensen et al.,

2003). The main assumption is that older adults, with their age-related limited future time perspective, show increased attention towards emotionally meaningful goals (Carstensen et al., 2003). Older adults might, therefore, rather engage in physical activity to experience immediate positive emotions instead of wanting to obtain a future goal (e.g., health benefits, better shape), which might come along with the endurance of negative emotions such as pain or feelings of discomfort (Löckenhoff & Carstensen, 2004). Studies on the relationship between autonomous motivation and physical activity provide supportive evidence: Ferrand et al. (2014) and Dacey et al. (2008) showed that highly self-determined older adults report higher levels of physical activity. Similarly, Lee et al. (2016) conducted a feasibility trial (N = 18) and found that intrinsic motivation influenced long-term adherence of community-dwelling older adults to physical activity. However, these studies are mostly cross-sectional and only a few interventions on the basis of self-determination theory exist for promoting older adults' physical activity (e.g., Pettersson et al., 2021). Including the concepts of the self-determination theory in the development of physical activity interventions in older adults could contribute to better adherence and thereby more sustainable long-term behavior change. In the development process of gLiFE, all three determinants of the self-determination theory, i.e., autonomy, competence, and relatedness, were considered when shaping gLiFE's teaching philosophy and mode of delivery. For example, LiFE and gLiFE participants are equipped with the principles of behavior change and habit formation to ensure their capability to manage their training autonomously in the long run.

1.3.4. Habit formation theory

Recently, automatic processes such as habits have received strong scientific interest in the context of health behaviors (Gardner et al., 2011; Orbell & Verplanken, 2020; Wood & Rünger, 2016). Although the concept of habits was already proposed in the 19th century by James (1887), research on the role of habits in the maintenance of health behavior has only gained momentum in the past two decades (Kwasnicka et al., 2016; Orbell & Verplanken, 2020; Rothman et al., 2009). In order to promote habit formation in the health context, many studies have been conducted to understand the habit formation process and to develop a theoretical framework for habit formation (Judah et al., 2013; Keller et al., 2021; Lally et al., 2010). Additionally, habit-based health behavior interventions in real-world settings have been conducted and evaluated (Gardner et al., 2014; Kaushal & Rhodes, 2015; Lally et al., 2008; Phillips et al., 2019).

Habit is defined as a process in which facing a cue – e.g., a specific physical context – automatically triggers an impulse for a specific action (Gardner, 2015; Wood & Rünger, 2016). To form a habit, a certain behavior needs to be repeated frequently in the same context in timely

proximity to a specific cue (Lally & Gardner, 2013). Through this frequent cue-dependent repetition, a mental context-behavior association builds, which then elicits the impulse for action with little conscious control when re-encountering the cue (Neal et al., 2012). Habitual behavior, in turn, is defined as any action which is controlled by habit (Gardner, 2015). Habits are assumed to promote behavioral maintenance due to their salience in the situational context, which leads to superiority over alternative actions (Adriaanse et al., 2011; see also Hagger, 2019) as well as their independence from motivation (Gardner et al., 2020; Rothman et al., 2009) and cognitive control (Kwasnicka et al., 2016; Orbell & Verplanken, 2020). This is also reflected in established measures of habit such as the *Self-Report Behavioral Automaticity Index* (Gardner et al., 2012), asking "The behavior XY is something I have no need to think about doing."

During the habit formation process, behavioral regulation gradually shifts from deliberate and conscious to automatic and impulse-driven, and *habit strength*, i.e., the extent to which a behavior has become habitual, increases (Lally et al., 2010; Wood et al., 2021). Habit strength typically increases asymptomatically over time, with steep increases in the beginning and the convergence towards stable levels. Studies show that the average duration for people to reach maximum levels of habit strength is around 2.5 to 3 months, with large differences between individuals (Keller et al., 2021; Lally et al., 2010). In the process of establishing a habit, motivational and volitional strategies, similarly to the HAPA, are assumed to guide behavioral regulation by enabling context-dependent behavioral repetition (Gardner & Lally, 2018).

When aiming for a target behavior to become habitual, two important steps include identifying an adequate contextual cue and planning for frequent behavioral repetition. Studies have shown that anchoring the target behavior around pre-existing daily routines such as eating (Lally et al., 2010) or personal hygiene (Judah et al., 2013) might facilitate habit formation. Further, planning as a volitional strategy could help to translate the intended habit formation into actual behavior (Fleig et al., 2013; Sniehotta et al., 2005). Implementation intentions (Gollwitzer, 1999) as a specific kind of planning have been proposed to be an effective means to form new habits (Hagger & Luszczynska, 2014). By linking the contextual cue and the target behavior within an if-then plans (e.g., "If I finish lunch, then I go for a brisk walk"), implementation intentions increase the awareness for the target behavior when being exposed to the contextual cue and thereby increase the probability for behavioral execution.

Habits in the context of physical activity have been the focus of theoretical considerations (Hagger, 2019; Rhodes & Rebar, 2018) and empirical studies (Fleig et al., 2013; Kaushal et al., 2017; van Bree et al., 2016). Two systematic reviews exist on the association between habit and physical activity, showing a moderate to strong relationship (r = .43, Gardner et al., 2011; r = .32, Rebar et al., 2016). Since physical activity needs to be performed regularly, is a relatively complex and time-consuming behavior, and can cause discomfort (Rhodes & Rebar,

2018), it is unlikely that longer physical activity sequences are fully habit-based and function completely without awareness. However, shorter physical activity sequences could be initiated or enacted habitually (Gardner et al., 2016). Since older adults experience decreases in aerobic capacity, they might profit from activities which would normally be considered low-intensity physical activity (Piercy et al., 2018) and increased walking duration (Klenk et al., 2013). Therefore, a suitable alternative to structured training could also be to form new, more active habits and enrich daily routines with short bouts of physical activity (Fleig, McAllister, et al., 2016; Stamatakis et al., 2019).

Since older adults often withdraw from physical activity interventions (see chapter 1.2.6), establishing habits which are *self-sustaining* (I. White et al., 2017) might be a promising way to foster physical activity sustainably in older adults. Few studies have examined physical activity habits in older adults so far. Findings from observational studies suggest that habits predict physical activity behavior in older adults better than social-cognitive variables such as intention (van Bree et al., 2015). Furthermore, two studies found contradicting evidence on the role of action planning in the context of older adults' physical activity and habit formation: whereas Fleig et al. (2013) showed that action planning and repeated exercising facilitated the translation of physical activity intention into habit, another study found that action plans were not necessary to translate intentions into habit (van Bree et al., 2016).

So far, only two habit-based interventions have been reported in the context of older adults' physical activity (Fleig, McAllister, et al., 2016; Gardner et al., 2014; I. White et al., 2017). The *On Your Feet to Earn Your Seat* trial (Gardner et al., 2014) was designed using a "small changes approach" to promote physical activity and reduce sedentary time in older adults. The intervention entailed 10 simple tips to integrate low-intensity physical activity bouts into daily routines. BCTs taxonomies were used to promote motivation to form a habit and to facilitate planning, self-monitoring, and context-dependent repetition. In a feasibility study of the On Your Feet to Earn Your Seat intervention, the intervention program had good acceptability and feasibility, but the participants in the intervention group did not show effects on physical activity and sedentary behavior over and above control group participants. Furthermore, habit strength of sedentary behavior decreased and physical activity increased in both the intervention and control group.

Another habit-based intervention is the Lifestyle-integrated Functional Exercise (LiFE) intervention (Clemson et al., 2010, 2012), a fall prevention intervention aimed at promoting the integration of functional balance and strength activities into daily routines (see chapter 1.5.1). The conceptual framework referred to habits as a key mechanism to promote behavior change in LiFE (Clemson & Munro, 2015). The effects of LiFE on habit strength were first examined in a feasibility trial which tested a group-based LiFE version in a sample of 13 middle-aged to higher-aged women, called EASY LiFE (Fleig, McAllister, et al., 2016). The findings suggest

that EASY LiFE is highly feasible and able to promote habit formation, indicated by above mid-scale values of habit strength at 6-month follow-up. Those two interventions adopt the idea of lifestyle-integrated training, which has been found to be acceptable in the target group of older adults (Weber et al., 2018; see chapter 1.2.6).

1.3.5. Chapter summary

This chapter displayed the theoretical foundations of health behavior change and habit formation. The HAPA was presented as an established behavior change model, along with its innovations and limitations. By addressing volitional concepts, the HAPA provides strategies to bridge the intention-behavior gap. However, the HAPA does not account for motivational quality, i.e., *why* individuals engage in a health behavior. Therefore, the presented thesis also takes into account self-determination theory as an additional health behavior theory. The self-determination theory offers a complementary explanation and proposes different motivational types. Furthermore, self-determination theory acknowledges the importance of basic psychological needs for successful behavior change and optimal well-being. Neither the HAPA nor self-determination theory considers implicit processes such as habits, which are seen as beneficial for behavioral maintenance. So far, few interventions exist which explicitly tackle habit formation as a desired outcome in the context of older adults' physical activity. The current work combines these three theories in the development and evaluation of the gLiFE format. First, the theories are mapped to the existing intervention content of LiFE, and then the health behavioral contents are broken down into small theoretical units, which are embedded into the gLiFE sessions (see chapter 4.2). The participants' perspective of the behavior change process is examined qualitatively (see chapter 4.3) and quantitatively (see chapter 4.5), and the changes in the theory-based psychological determinants of behavior change are examined (see chapter 4.6).

1.4. The Design and Evaluation of Health Behavior Interventions

Since the current work has the goal of developing the group-based LiFE intervention with a focus on behavior change, the theory and empirical evidence of the functioning of health behavior interventions was helpful, along with recommendations on how to develop and evaluate complex interventions such as LiFE.

Lifestyle changes, like the adoption of a more active lifestyle, can prevent or delay many health risk factors and improve both physiological and psychological well-being (Marquez et al., 2020; Piercy et al., 2018; Warburton & Bredin, 2019). Especially in older adults, who are the most inactive compared to other age groups (Lange & Finger, 2017), even small increases in or light levels of physical activity have been found to induce beneficial health effects (Dipietro et al.,

2019; Klenk et al., 2013; Stamatakis et al., 2019).To change behavior effectively, health behavior interventions to promote individuals' behavior are the means of choice (Hagger, Cameron, et al., 2020).

Many interventions to alter health behaviors have, however, been designed with little focus on how and why interventions work, leaving interventions poorly specified (S. D. French et al., 2012) and creating the impression of interventions as "black boxes" (Hagger et al., 2020). In recent decades, scientific efforts have advanced toward developing theory-based interventions and unpacking the mechanisms which render interventions effective (Bartholomew Eldredge et al., 2016; Michie et al., 2011).Today, guidelines exist on how to develop and evaluate complex interventions (Craig et al., 2008; Moore et al., 2015; Skivington et al., 2021). The current work is, from a methodological viewpoint, conducted along these guidelines.

This chapter provides an overview of the basic reasoning behind health behavior interventions, their design, and their evaluation. Furthermore, this chapter will address the importance of a theoretical basis for health behavior interventions and display empirical studies in the context of older adults' physical activity. After providing the "technical details" of intervention development, refinement, and evaluation, this chapter will give empirical examples of how physical activity interventions in older adults have been evaluated regarding their effectiveness and their theory-based intervention content.

1.4.1. How behavior change interventions (are assumed to) work

Behavior change interventions are defined as "coordinated sets of activities designed to change specified behaviour patterns" (Michie et al., 2011, p.1). Changing complex health behaviors like physical activity requires the application of *complex interventions*. A complex intervention, as defined by Craig et al. (2008), entails several interacting components, can be applied to facilitate different numbers of health behaviors, can be led by different groups or organizations, can be applied to promote diverse outcomes, and can be tailored to different degrees. To properly design and evaluate complex interventions, it is important to understand how interventions are assumed to exert their effects.

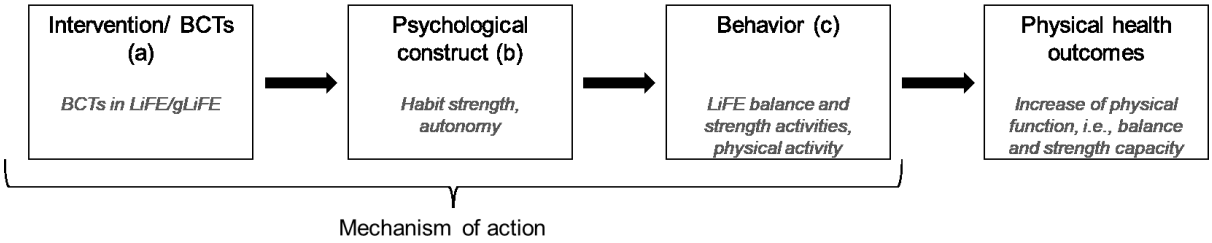
There are two possibilities to explain the functioning of health behavior interventions. First, researchers can identify the active ingredients of existing interventions to understand how and why they work. However, the poor reporting of existing health behavior interventions has been criticized (Rothman et al., 2020), making a standardized investigation of effective intervention components challenging. In recent decades, standardized frameworks to report interventions such as the BCT taxonomy v1 (Michie et al., 2011) have been developed. A BCT is defined as the smallest intervention component altering or directing behavioral regulation. Furthermore, BCTs should be replicable in other applications of the behavioral intervention and each BCT applied should contribute to intervention effectiveness (Michie et al., 2011). The value of using

BCTs lies in better understanding the active ingredients of behavioral interventions and thereby facilitating both standardized selection and evaluation of interventions (Michie & Johnston, 2013). Although more and more intervention studies are comprised of lists of implemented BCTs (e.g., as recommended by the TIDieR checklist; Hoffmann et al. 2014), publications often lack a rationale for the theoretical derivation of those BCTs or make assumptions about their effect on the target behavior (Carey et al., 2019).

Second, on the basis of theoretical frameworks like the BCT taxonomy or the intervention mapping approach (Kok et al., 2016), behavioral interventions can be developed from sketch and evaluated more systematically. The "range of theoretical constructs that represent the processes through which a BCT affects behavior" are termed *mechanisms of action* (Michie et al., 2018, p.502). Figure 5 depicts how a BCT can potentially induce behavior change. For the most part, BCTs first affect psychological mechanisms such as motivation or self-regulation, and then induce behavioral changes, e.g., increased walking duration per day, which also translate into physiological outcomes, e.g., increased stamina or leg strength (Hagger et al., 2020). In some cases, BCTs can also affect the target behavior directly, e.g., BCT 12.6 *Body changes* could mean providing participants with a hearing aid so that they can better understand the trainer (Hagger et al., 2020).

Figure 5

Mechanism of Action for Health Behavior Interventions via Psychological Constructs With Examples for the (g)LiFE Intervention



Note. Mechanisms of action can include the pathway from the intervention/BCTs via psychological constructs to behavior (a→b→c) or can include the direct path from intervention/BCTs to behavior (a→c). This dissertation only establishes the association between the intervention and psychological determinants of behavior change (a→b).

1.4.2. Theory-based behavior change interventions

Describing the mechanisms which are assumed to initiate behavior change has been proposed as a prerequisite for behavior change interventions (Abraham & Denford, 2020). To do so, a sound theoretical basis and a translation into behavior change techniques is needed. This theoretical basis includes, but is not limited to, theories such as the HAPA, self-determination theory, and habit formation theory. However, researchers claim that the derivation of BCTs is

often not reported or used in intervention development (Carey et al., 2019; Prestwich et al., 2014). Mixed evidence exists for the relationship between the existence of a theoretical basis and intervention effectiveness. A systematic review showed a positive relationship between physical activity and dietary interventions which contain groups of BCTs associated with a behavior change theory and intervention effectiveness (Dombrowski et al., 2012). Meanwhile, a systematic review of systematic reviews on randomized controlled trials (RCT) of behavior change interventions concluded that theory-based interventions are not more effective than non-theory-based interventions (Dalgetty et al., 2019). However, the authors point towards methodological flaws, such as the risk of publication bias, which might decrease the "true effect" of theory on effectiveness in behavior change interventions. Similarly, a meta-analysis on effectiveness of theory-based vs. no-stated-theory physical activity interventions revealed that a theoretical basis alone does not improve effectiveness (McEwan et al., 2019). However, this kind of comparison is often inappropriate. As already mentioned, many health behavior interventions lack a sound theoretical basis. Even if interventions are explicitly based on a theory, less than half of the interventions link at least one BCT to at least one hypothesized mechanism of action and only about 10% link all theory-relevant constructs to at least one BCT (Prestwich et al., 2014). Thus, the mention of a theory does not ensure that the intervention builds on a strong theoretical basis. Comparing theory-based vs. no-stated theory interventions is therefore not a good test of the theory effectiveness hypotheses. Overall, results suggest that theory-based physical activity interventions might produce more reliable results than non-theory-based interventions, if the intervention development is fully based on the theoretical model. This is why gLiFE was developed along empirically established health behavior theories such as the HAPA, self-determination theory, and theory on habit formation.

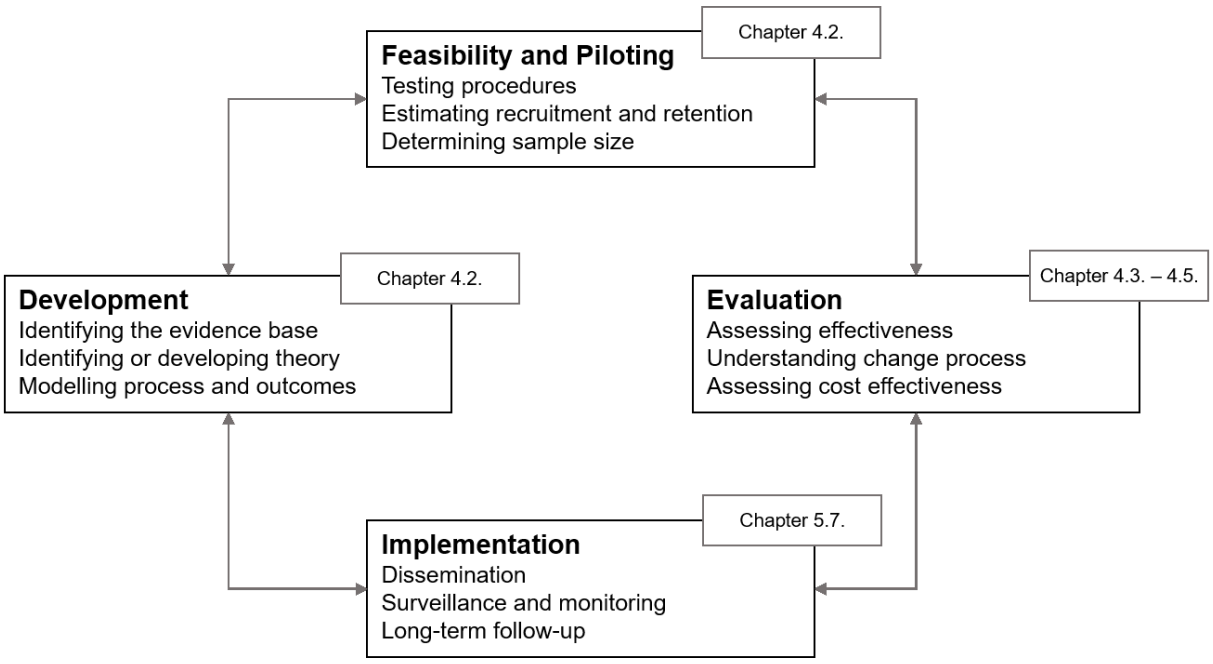
1.4.3. Guidelines on the development, refinement, and evaluation of health behavior interventions

(Health behavior) interventions can be quite complex. Therefore, guidelines exist to support and structure the intervention development process. The MRC guidelines for the development and evaluation of complex interventions (Craig et al., 2008), which were updated recently (Skivington et al., 2021), propose that intervention development and evaluation may be a cyclic rather than a linear process, i.e., allowing reiterations along the process (Figure 6). For example, feedback from stakeholders could elicit intervention refinement along the development process (O'Cathain et al., 2019). When developing an intervention, researchers should make use of the best evidence available and choose the most appropriate theory. Specifying how the intervention could potentially cause change through modeling processes and outcomes is considered important to evaluating the intervention later. Pilot studies could reveal potential

challenges, for example regarding feasibility in the target group (Craig et al., 2008). After testing the intervention in a series of pilot studies, interventions should be evaluated in an exploratory and definite manner. At the end, ideally, the intervention can be implemented under monitoring on a large scale. In the case of the current work, gLiFE was tested in an initial feasibility study (see chapter 4.2) before testing it against the one-to-one format on a larger scale (see chapter 4.4). Furthermore, the dissemination of the study results and advances to implement gLiFE on a larger scale are currently being carried out (see chapter 5.7).

Figure 6

Key Elements of the Development and Evaluation Process (Craig et al., 2008)



Note. The small boxes contain references to the presented thesis. The development and initial feasibility testing of gLiFE is reported in chapter 4.2. The evaluation of gLiFE regarding effectiveness (chapter 4.3 and 4.4), participants' perspective (chapter 4.3 and 4.5), and effects on psychological determinants of behavior change (chapter 4.6) are reported in the indicated chapters. The planned and undertaken advances on disseminating gLiFE are summarized in chapter 5.7.

Aside from intervention development, interest in intervention *refinement* has risen in recent years. This is especially helpful in areas such as physical activity promotion, where many interventions already exist, and developing an intervention from sktech including rigorous testing would be a waste of already invested resources. Refinement or adaptation is assumed to be a deliberate process in which the design or delivery of an intervention is altered to increase its effectiveness in or fit to a specific context (Wiltsey Stirman et al., 2019). For example, existing interventions could be better adapted to the target population in a refinement process. Evidence from systematic reviews suggests that interventions which are tailored to the characteristics and needs of the target group are more effective (McEwan et al., 2019; Noar et al., 2007).

Older adults, who typically show high heterogeneity in their needs and capabilities, could especially profit from program adaptations and tailoring (Klusmann et al., 2021; Ziegelmann & Knoll, 2015). To systematically report intervention refinements, frameworks such as the framework for reporting adaptations and modifications-expanded (FRAME) have been proposed (Stirman et al., 2013; Wiltsey Stirman et al., 2019). By using FRAME, intervention modifications can be described regarding their rationale and their target.

After an intervention is developed or refined, it needs to be evaluated to judge its value (Matthews & Simpson, 2020). There are various levels on which behavior change interventions can be evaluated, for example outcome evaluation, process evaluation, or economic evaluation (Matthews & Simpson, 2020). Regarding the stage of intervention development, it can either be evaluated under highly controlled (i.e., efficacy) or real-world conditions (i.e., effectiveness). To examine intervention effectiveness, a single primary outcome and a few secondary outcomes with a long-term follow-up are seen as most convenient (Craig et al., 2008). Aside from the evaluation of outcomes, a *process evaluation* can help to clarify casual mechanisms of how the intervention works, assess the quality of implementation, and identify contextual factors, for example, under which circumstances the intervention is assumed to work (Moore et al., 2015; Figure 7). Furthermore, before conducting a *full* evaluation, feasibility studies can be used to evaluate the intervention along the development process (O'Cathain, Croot, Duncan, et al., 2019). A recent categorization of intervention evaluation states five potential evaluation outcomes: stakeholders, program theory, context, economic considerations, and implementation (Matthews & Simpson, 2020). Evaluating the stakeholders' perspective can, for example, provide important insights on the acceptability of an intervention (Sekhon et al., 2017). Furthermore, Matthews & Simpson (2020) also point out that the refinement of the program theory could be considered as a study outcome. To sum up, development and evaluation of complex interventions are processes which involve a multi-step procedure dependent on the research question and study design.

1.4.4. Evaluations of interventions to change older adults' physical activity behavior

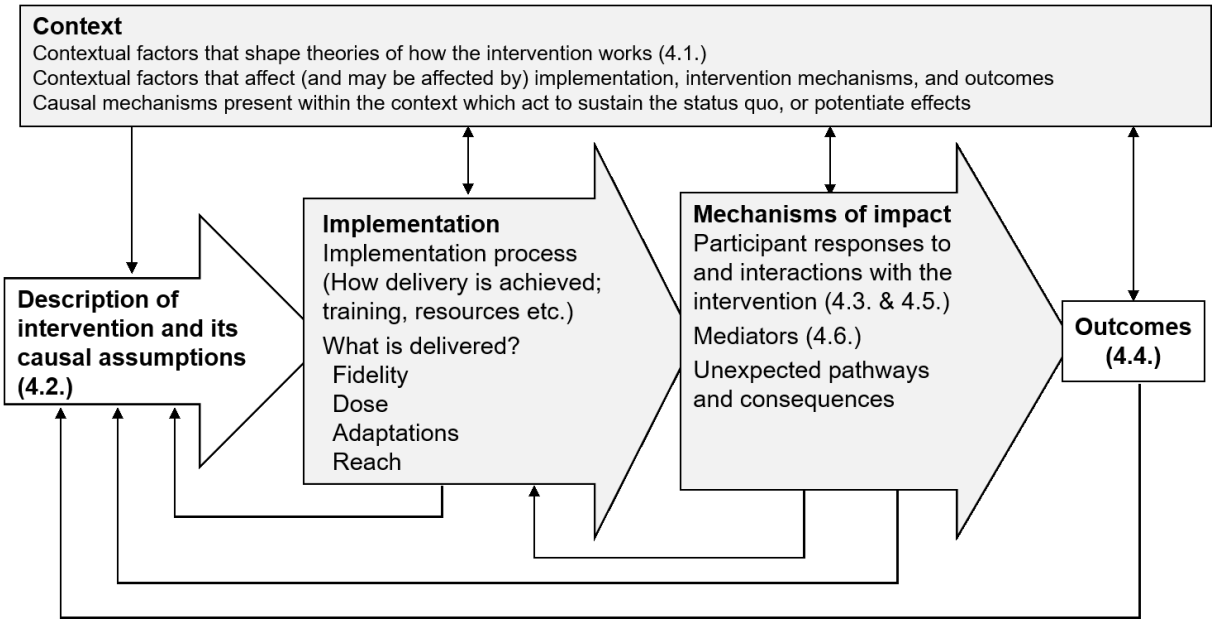
Having provided the technical details of intervention development, refinement, and evaluation, this chapter provides empirical examples of how physical activity interventions in older adults have been evaluated regarding their effectiveness, their theory-based intervention content, as well as their mechanisms of impact.

So far, few studies have investigated active ingredients (BCTs) and mechanisms of action of exercise interventions in older adults. Arnautovska et al. (2018) identified several BCTs and aspects of the implementation of physical activity interventions which are perceived as helpful by the target group. Behavioral demonstration with practice and self-monitoring were identified

as helpful strategies for the facilitation of physical activity habits. Regarding program implementation, participants considered features like face-to-face contact, low costs, age-appropriate physical activity levels, and tailored content to be important.

Figure 7

Schematic Model of Process Evaluation (Moore et al., 2015)



Note. This model depicts key functions of process evaluation and relations among them (grey boxes are key components of a process evaluation). The numbers in brackets indicate the chapters of the current work where the respective step of process evaluation is reported. The application of the HAPA to older adults' physical activity behavior as a preparatory or contextual work is reported in chapter 4.1. The gLiFE concept and a detailed description of the gLiFE intervention is reported in chapter 4.2. Regarding mechanisms of impact, chapter 4.3 and 4.5 report the participants' perspective on gLiFE's acceptability and program-specific aspects in comparison with LiFE with qualitative and quantitative means, respectively. The effects of gLiFE on falls-adjusted physical activity in comparison to LiFE is reported in chapter 4.4.

Zubala et al. (2017) conducted a systematic review of reviews on physical activity interventions in community-dwelling older adults. Ten reviews reported that interventions were based on a theoretical framework, but no mechanisms of action were examined. All 19 reviews contained elements of BCTs, but only two used the BCT taxonomy (Michie et al., 2011). Of these two reviews, one focused on intervention features (BCTs and delivery) which are associated with long-term effectiveness of physical activity interventions (O'Brien et al., 2015). The other review investigated the effects of BCTs on self-efficacy and physical activity in older adults (French et al., 2014). In another systematic review and meta-analysis on long-term sustainability of physical activity in older adults (Sansano-Nadal et al., 2019), nine studies were identified which included specific intervention strategies to enhance the long-term sustainability of physical activity. Those intervention strategies were not specifically entitled as BCTs, but were mostly linked to self-control, self-efficacy, and behavioral capability constructs grounded in

social cognitive theory. In a fourth systematic review, combined group and home-based exercise programs for fall-prone older adults were investigated regarding their effectiveness, adherence and utilized BCTs (Teng et al., 2020). The authors provide a list of the BCTs most frequently applied, but do not link them to mechanisms of action or health psychological theories. Lastly, a systematic review focused on physical activity interventions which were based on the theory of planned behavior found that 26 out of the 93 BCTs were used in those interventions (Senkowski et al., 2019). Given these findings, more research is needed on the systematic reporting and evaluation of physical activity interventions in older adults to understand the underlying processes and effects.

1.4.5. Chapter Summary

This chapter provided an overview over the development and evaluation of complex interventions. Due to the poor reporting of health behavior interventions, taxonomies such as the BCT taxonomy (Michie et al., 2011) have been proposed to streamline the development and evaluation of behavioral interventions. Both development and evaluation are multi-step processes which can profit from frameworks such as the MRC guidelines for the development and process evaluation of complex interventions (Craig et al., 2008; Moore et al., 2015). With regard to older adults' physical activity, evidence suggests that the existing interventions are mostly not reported in line with the recommended guidelines and lack an in-depth investigation of mechanisms of action. Therefore, compared to LiFE, gLiFE was developed and evaluated alongside the MRC guidelines for the development and evaluation of complex interventions with a focus on psychological determinants of behavior change.

1.5. The Lifestyle-integrated Functional Exercise (LiFE) Intervention

Given an aging global population, effective fall prevention and physical activity promotion in older adults in the form of tailorable interventions which ideally induce long-term effects are urgently needed. Clemson et al. (2010) developed an intervention for fall-prone, community-dwelling older adults called Lifestyle-integrated Functional Exercise (LiFE). This chapter provides an overview over the LiFE intervention, its approach, advantages, and challenges.

1.5.1. The LiFE approach

The LiFE intervention is a tailorable, habit-based fall prevention and physical activity promotion program for older adults at risk of falling (Clemson et al., 2012). LiFE adds complexity and movement to daily routines of older adults living in modern societies, where automation makes physical stress and labor dispensable. The idea to incorporate exercise into daily routines was not new (Andersen et al., 1999; Dunn et al., 1999; Opdenacker et al., 2008), but LiFE first applied the principle of lifestyle-integration to the target group of fall-prone older adults. By linking the so-called LiFE activities to daily routines, older adults are proposed to develop new,

more active movement habits. Thereby, training ought to take place frequently throughout the day, as opposed to structured training approaches. For the target group of fall-prone older adults, functional balance and strength activities have been shown to be most efficient (see chapter 1.2.6), which is why LiFE entails 14 balance and lower limb strength activities, such as the one-leg stand or rising from a chair (Clemson et al., 2014). To not only prevent falls but also increase physical activity, LiFE also contains two principles for physical activity promotion: *move more* and *sit less*. Thus, the goal of LiFE is to prevent falls and promote physical activity simultaneously.

LiFE exceeds structured fall prevention or physical activity interventions for older adults because it teaches the principles of balance and strength training such as *reduce the base of support* or *load your muscles* alongside the actual LiFE activities. LiFE participants also learn how to upgrade the LiFE activities (e.g., by combining two principles) to adapt the training to their individual progress. In doing so, LiFE aims to self-empower participants to manage their training individually in the long term. With the help of the so-called activity planner, participants can record and keep track of their LiFE activities.

1.5.2. Testing LiFE against other interventions – the original trial

In the original RCT, Clemson et al. (2012) compared LiFE (*n* = 107) to both a structured program (*n* = 105), which was carried out three times a week, and a sham intervention (*n* = 105) regarding effectiveness and adherence. The structured program contained balance and lower limb strength exercises and was performed using ankle cuff weight. Both LiFE and the structured program were taught over seven sessions and two booster phone calls. The sham intervention program contained gentle exercises and was taught over three sessions and six follow-up phone calls. LiFE resulted in a falls incidence reduction of 31% (incidence rate ratio [IRR] 0.69; 95% CI 0.48 to 0.99) when compared to the sham intervention. The structured training did not result in a significant falls incidence reduction when compared to the sham intervention (IRR 0.81; 95% CI 0.56 to 1.17). After 12 months, 68 LiFE participants (64%) still exercised, compared with 56 participants (53%) in the structured training group or 56 participants (53%) in the sham intervention group. Given these positive findings, it is conceivable that many older adults could profit from the LiFE program if it was implemented on a larger scale.

1.5.3. Challenges of LiFE

Although LiFE has shown to be effective in reducing falls and increasing physical activity, both the research on the effectiveness as well as the delivery format have their challenges. An important factor is that LiFE is highly intrusive, i.e., older adults are asked to adapt their daily routines, which they might have established over years or even decades. Assessing the acceptability of the LiFE intervention in the target group could bring helpful insights, since acceptability is linked to intervention effectiveness (Sekhon et al., 2017). Furthermore, it remains

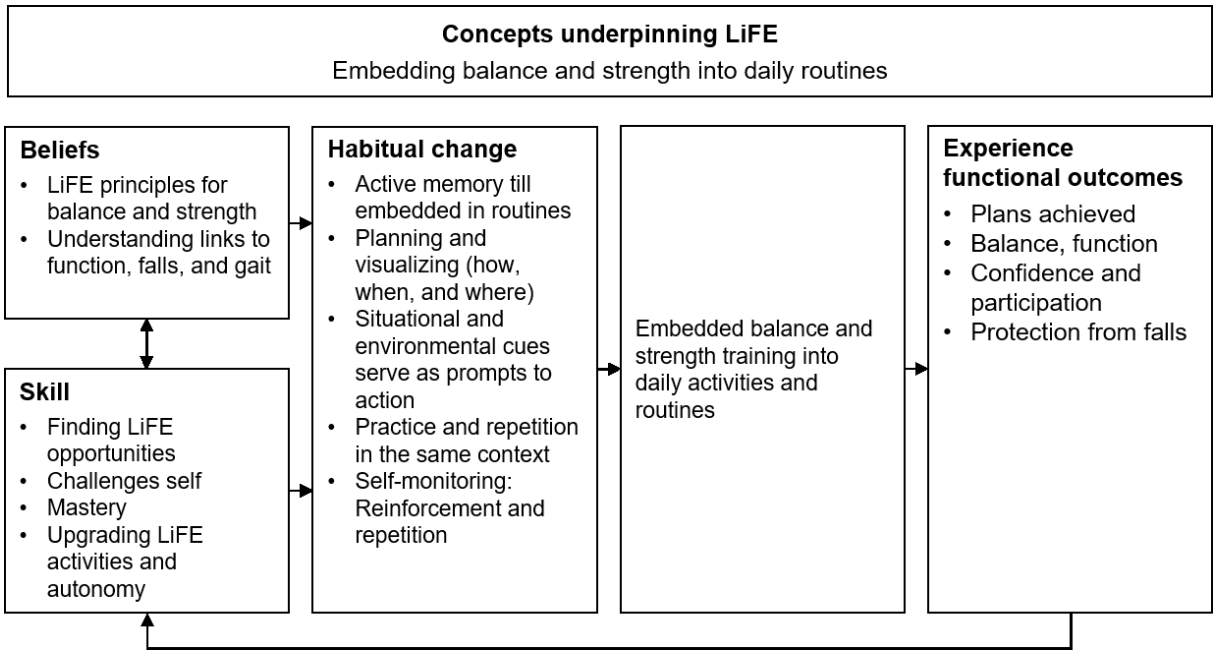
unclear *how* the LiFE intervention induces its effects, for example whether and to which extent habits are established through participating in LiFE. The biggest challenge for the LiFE intervention to be implemented large-scale is, however, its resource intensive format of delivery. LiFE is delivered via seven individual sessions at participants' homes by trained personnel. Such a resource-intensive format might not be reimbursed by health care systems. Transferring LiFE to a more resource-saving group format might improve its accessibility to a larger group of older adults.

1.5.4. Conceptual LiFE model

LiFE's original conceptual model (Clemson & Munro, 2015) was created to describe the meanisms beyond LiFE by using a process model as done in behavior change theories. In the model, habitual change was assumed to take place via changing beliefs (e.g., knowledge of the LiFE principles for balance and strength and their links to falls, gait, and function) and skills (e.g., finding LiFE opportunities, challenging self, mastery, upgrading the LiFE activities, and autonomy; Figure 8).

Figure 8

Conceptual Model of LiFE (Clemson & Munro, 2015)



By linking the LiFE activities to certain daily tasks, older adults were proposed to experience functional outcomes (e.g., achieved plans, balance, function, confidence and participation, and protection from falls). Having been created by ergo therapists, the conceptual model of LiFE

already considered several important psychological constructs such as habit, planning, motivation, and self-efficacy. The importance of cues for habit formation was well-explained and good examples were provided.

Although the conceptual model was innovative for the time and field of research, it has three major challenges from the health psychological perspective. First, the terminology used in the conceptual model was vague. Excepting the theory on habit formation (Lally & Gardner, 2013), the concept did not refer to other behavior change theories, although concepts such as self-efficacy or planning can clearly be linked to the HAPA. Furthermore, although autonomy was explicitly mentioned (p.6), no link was drawn to the self-determination theory. For example, the statement “brief but targeted explanations about how the type of exercises directly link to beneficial outcomes can impact motivation” (p.4) could have also been stated using the terminology from the self-determination theory: “increasing participants’ feeling of competence and mastery towards the LiFE program by providing information on the effect of the LiFE activities on functional outcomes can foster autonomous motivation”. Second, the strategies used in the intervention were not exhaustively listed and not formally categorized, e.g., by using the BCT taxonomy (Michie et al., 2011). The above mentioned brief explanations could have, for example, been linked to the BCT 5.1 *Information about health consequences*.

Third, and linked to the first two challenges, no information was given on how to test the assumptions made in the conceptual model. Thus, it remained unclear how LiFE affected the psychological mechanisms which then induced increased levels of physical activity and reduced fall rates. For example, despite the fact that LiFE aims to promote habit formation, it was unclear which BCTs were used to do so. Furthermore, it is yet to be tested whether the LiFE activities actually become habitual and habit strength is maintained over time. Understanding why LiFE has shown to be superior to structured training regarding behavioral changes and adherence is an important step in research and could ensure a successful implementation of LiFE. This is why the presented thesis examines the psychological determinants which are assumed to lead the behavior change process, such as habit formation. The methods used to do so are described in chapter 3.3.

1.5.5. Chapter summary

In the LiFE approach, the concept of lifestyle-integrated training is applied to the context of fall prevention in community-dwelling older adults. New, more active movement habits are assumed to form through the integration of functional balance and strength activities into daily routines. A large RCT showed the effectiveness of LiFE regarding fall reduction and physical activity improvement compared to both a structured training and a sham intervention group. So far, the delivery format, which includes seven individual home visits, is not feasible for large-

scale implementation. Furthermore, the conceptual model of LiFE has yet to be tested and linked to the BCT taxonomy, leaving it unclear how LiFE induces habit formation.

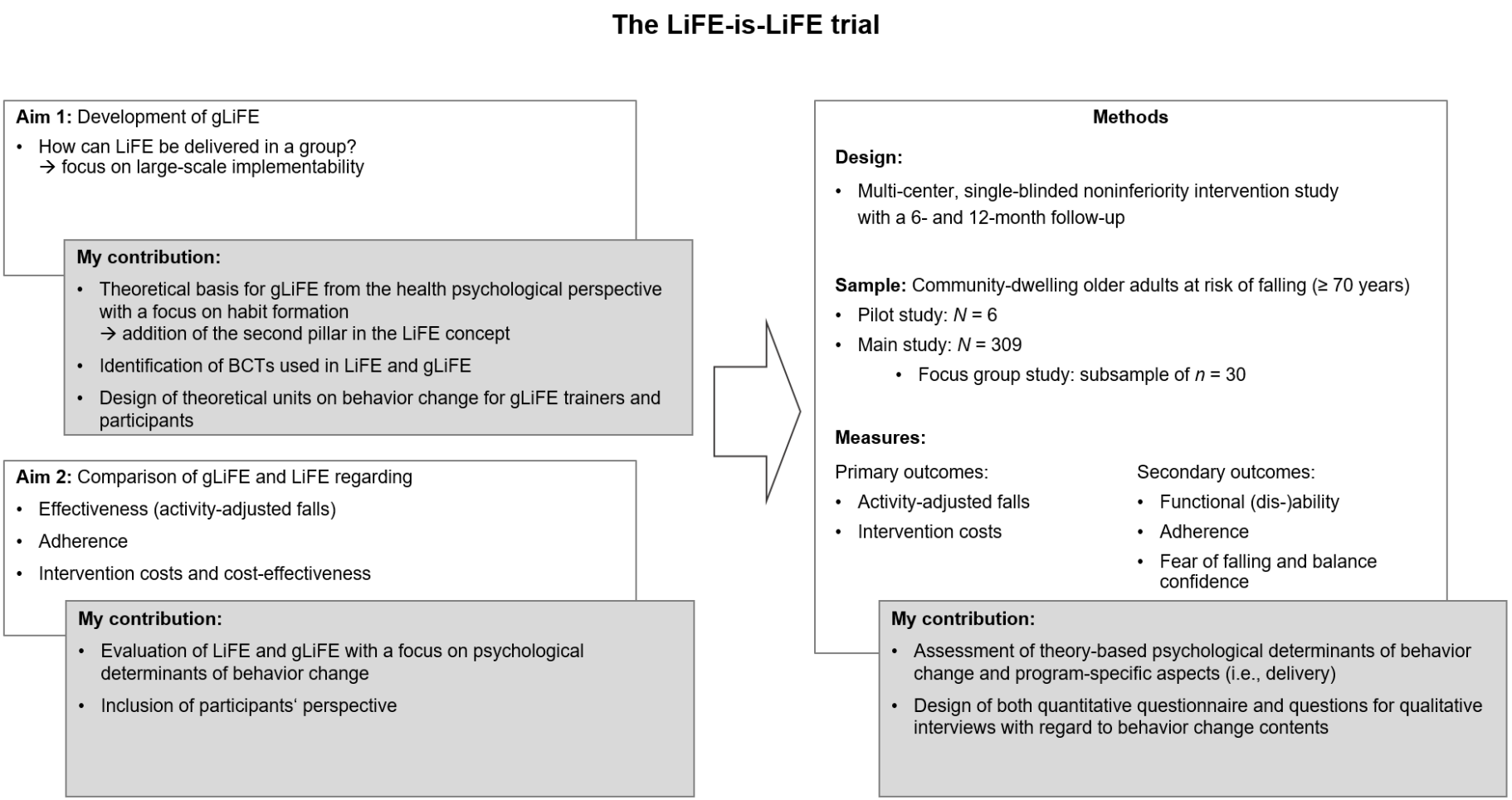
2. Aims of this Dissertation Project

The goal of the current work is the theory- and evidence-based development and evaluation of gLiFE from a health behavior change perspective. A major issue for the current work has been that the behavior change process initiated through LiFE did not get enough attention previously, leaving it unclear how LiFE develops its effectiveness and whether habits are actually established trough LiFE. Therefore, in the course of developing and evaluating gLiFE, psychological aspects on behavior change were explicitly considered and examined. The presented thesis is mainly driven by two questions: a) How can gLiFE best be delivered for promoting long-term behavior change and habit formation? and b) How does gLiFE work compared to LiFE? This second aspect, considered as the intervention evaluation, exceeds assessing clinically relevant outcomes. Thus, this work, according to the current Medical Research Council (MRC) guidance for the development (Craig et al., 2008) and process evaluation (Moore et al., 2015) of complex interventions, also considers psychological outcomes and the participants' perspective. Figure 9 depicts the aims and methods of the LiFE-is-LiFE trial and the contribution of the current work.

By strengthening the theoretical basis of behavior change in gLiFE through the application of the HAPA, the self-determination theory, and habit formation theory and evaluating LiFE and gLiFE on the behavioral and psychological level, this work contributes to deeper understanding of the underlying psychological processes, such as whether and to which extent habits are established in (g)LiFE. These new insights could, in turn, contribute to the effectiveness of LiFE as an important step towards successful large-scale implementation and evaluation.

Figure 9

Aims and Methods of the Life-is-Life Trial and Contribution of the Presented Thesis



2.1. Overview of the Papers Included

This dissertation includes six publications, of which five include the development and evaluation of gLiFE (see Figure 1). All publications are based on the LiFE-is-LiFE sample (see chapter 3.4). The current work was conducted within the course of the LiFE-is-LiFE project (Jansen et al., 2018), a multi-center, single-blinded, randomized, non-inferiority trial conducted within an interdisciplinary team of researchers. The trial was originally set up to examine whether a newly developed group-based LiFE (gLiFE) format is as effective as the resource-intensive one-to-one format (Jansen et al., 2018).

In the first publication (chapter 4.1) was a preparatory piece and applied the HAPA to older adults' walking behavior. Using the baseline sample of the LiFE-is-LiFE trial, it was investigated whether intrinsic motivation as a measure of motivation quality can provide additional value to explain older adults' sensor-measured walking duration.

In the second publication (chapter 4.2), the conceptual gLiFE framework was presented. The original conceptual model was revised with a stronger focus on theories of behavior change and the BCTs. Important features for large-scale implementability such as an optimized trainer-participant ratio, portable low-cost material, and comprehensive units of complex behavior change content were considered in the design of gLiFE. The development process resulted in a gLiFE trainer's manual. Mixed-method results from the feasibility testing were also presented.

In the third publication (chapter 4.3), LiFE and gLiFE were evaluated from the participants' perspective qualitatively. Acceptability, a concept which has shown to be related to adherence and intervention effectiveness, was the focus of the evaluation. Within four focus group discussions with a subsample of participants (n = 30), participants' experiences regarding LiFE's and gLiFE's acceptability were compared.

In the fourth publication (chapter 4.4), the primary and secondary outcomes of the LiFE-is-LiFE trial were reported. Non-inferiority of gLiFE compared to LiFE regarding activity-adjusted falls was determined, and intervention costs of both interventions were compared. Due to the onset of the Covid-19 pandemic, the 6-month follow-up was used instead of the 12-month follow-up.

In the fifth publication (chapter 4.5), the participants' perspective on LiFE and gLiFE at 6- and 12-month follow-up was examined using quantitative questionnaires. The aim of this study was to investigate whether participants' evaluations differed between formats and over time. Both formats were evaluated regarding the overall satisfaction of participants, how they perceived the effectiveness, and how they liked more program-specific aspects such as the mode of delivery, materials, and contents.

In the sixth and final publication (chapter 4.6), the effects of LiFE and gLiFE on psychological determinants of behavior change were examined. Previously, it was unclear whether the set of BCTs used in LiFE are actually able to induce changes in psychosocial determinants of behavior change. Therefore, multiple potential psychological determinants of behavior change were chosen to understand how LiFE, and the new gLiFE format, induce their effects. By using motivational and volitional determinants, habit strength as the determinant for behavioral change and automaticity, and more general determinants derived from the self-determination theory, the effects of LiFE and gLiFE were analyzed over time and between intervention formats.

In summary, this dissertation project is based on standards for the development (Craig et al., 2008) and evaluation (Moore et al., 2015) of complex interventions. This research facilitates a better understanding of the psychological aspects and mechanisms behind fall prevention and physical activity promotion in older adults. More detailed publication summaries are included in chapter 4.

3. Methods of the LiFE-is-LiFE Trial and the Presented Thesis

Being part of an interdisciplinary research project, the current work is embedded in the LiFE-is-LiFE trial. Since the basic methodology in the mother trial is equal in the current work, the rationale and methodology of the LiFE-is-LiFE trial will be explained first. Thereafter, an overview over the specific methodology of the presented thesis will be given.

3.1. The LiFE-is-LiFE Trial: Non-inferiority Testing of the Group-Based Life Intervention

The LiFE-is-LiFE trial (grant number 01GL1705A-D) was a randomized, single-blinded non-inferiority trial set up to a) develop a group-version of the LiFE program and b) compare it to the original LiFE format regarding its effectiveness and costs (Jansen et al., 2018). Non-inferiority trials are normally used in pharmacological studies to examine whether a new medication is not less effective than an existing one (Piaggio et al., 2010). Applying this study design to test the effective LiFE intervention against a group-based LiFE (gLiFE) approach, which is potentially less resource-intensive, could confirm gLiFE's non-inferiority to LiFE and thereby help to make the LiFE approach more feasible for large-scale implementation. Because health insurances and potential providers of gLiFE have restricted reimbursement schemes, the cost-effectiveness analysis conducted within the LiFE-is-LiFE trial was another important step towards large-scale implementation (Peeters et al., 2011; Sach et al., 2012).

3.1.1. Former group-based LiFE approaches

Previous to the LiFE-is-LiFE trial, three attempts were made to transfer LiFE to the group context (Fleig, McAllister, et al., 2016; Gibbs et al., 2015, 2019; Li et al., 2018). Gibbs et al. (2015) first developed a mixed LiFE intervention (Mi-LiFE) containing one individual home visit, four group sessions, and two phone calls in the primary care context in older adults aged 75 years and over. In their feasibility study, where recruitment, retention, and adherence were examined over 6 months, Mi-LiFE showed to be feasible. Results revealed no significant changes in physical activity, but participants reported improved levels of perceived balance, strength, and health-related quality of life (Gibbs et al., 2019).

Fleig et al. (2016) conducted a mixed method pre-post design study in which they tested a group-based LiFE format (EASY-LiFE) consisting of seven sessions and two booster phone calls. Three trainers (one exercise physiologist, one personal trainer, one health psychologist) delivered EASY-LiFE to a group of 13 middle-aged to older women (M_{age} = 66 years). By putting a stronger focus on theory-based psychological determinants of behavior change, they showed increases in action planning, action control, and habit strength but no changes in intention, self-efficacy, and coping planning. Within the focus group interview, participants reported to like EASY-LiFE and appreciated the interaction with peers.

The last pre-existing group LiFE format by Li et al. (2018) conducted a single-group quasi-experimental study (N = 16) with a modified LiFE version in older adults aged 65 years and older living in residential communities. Their intervention was designed to be delivered to groups of six to ten participants within six sessions delivered by two trainers, followed by two individual phone calls. Results revealed that after 26 weeks, 13 remaining participants (M_{age} = 88 years) showed significant increases in lower body strength and balance, but results on fall risk reduction were inconclusive. Regarding adherence, participants reported continuing to practice LiFE at follow-up.

All studies provided important insights for advancing the design of a group-based LiFE format in the context of the LiFE-is-LiFE trial. To achieve low resource-intensity, however, the remaining home visit in the Mi-LiFE format (Gibbs et al., 2015) or trainer-participant ratio of 1:4 in EASY-LiFE (Fleig, McAllister, et al., 2016) may not be feasible. The results of Li et al. (2018) were promising, especially considered the high mean age of the sample. However, little information was provided on the delivery itself, and the small sample size renders a test in a larger sample mandatory.

3.2. Methods of the LiFE-is-LiFE Trial

The LiFE-is-LiFE trial was set up to investigate whether a group-based LiFE format can be as cost-effective as the individual LiFE (Jansen et al., 2018).To test the newly developed gLiFE format against the original format, the LiFE-is-LiFE trial aimed at a sample of N = 300 (n_{LiFE} = 150, n_{gLiFE} = 150) community-dwelling older adults aged 70 years and older. Sample size was calculated on the basis of a non-inferiority margin of 20%, additionally considering a drop-out rate of 25% and a safety margin.

Participants were recruited between June 2018 and May 2019 via a two-step screening procedure (telephone and in-house) at the Network Aging Research, University of Heidelberg, Germany and the Robert-Bosch-Hospital, Stuttgart, Germany (Figure 10). Study information was sent to older adults aged 70 years and older via municipal registration offices. Additionally, the study was advertised via flyers, journal articles, public talks, and with the help of a health insurance company. Older adults were eligible if they had either a) experienced at minimum one injurious or more than one non-injurious fall in the year prior to the study or b) were at risk of falling, indicated by a perceived balance decline and a score time of ≥ 12 seconds for the *Timed Up-and-Go* test (Podsiadlo & Richardson, 1991). Exclusion criteria were, among others, the inability to walk at least 200m without personal assistance, too high levels of physical activity (i.e., structured training more than once a week or more than 150 minutes of moderate to vigorous physical activity per week), severe cognitive impairment (Montreal Cognitive Assessment < 23; Nasreddine et al., 2005) or severe cardiopulmonary or neurological conditions.

A full list of inclusion and exclusion criteria is provided in Table 1. Ethical approval was obtained for both study centers, and informed consent was taken at the in-house screening.

Table 1

Inclusion and Exclusion Criteria of the Life-Is-Life Trial

Inclusion criteria	Exclusion criteria
Age ≥ 70 years	Participation in a structured sports program once per week in the past 3 months
Community-dwelling *OR* "assisted living" without active help	Moderate to vigorous physical activity > 150 minutes/week in the past 3 months
During the past 12 months: > 2 falls *OR* 1 injurious fall *OR* Subjective balance decline AND TUG time > 12 sec	Medical conditions: - Heart Failure (NYHA Stage III & IV) - Stroke (< 6 months) - Parkinson's - Acute cancer therapy (in the last 6 months) - COPD (Stage III & IV) - Unstable fracture of extremities - Lower limb amputation - Acute depression - Uncontrolled resting systolic blood pressure of > 160 and - resting diastolic blood pressure of > 100 or greater
Able to read and write in German	Moderate to severe cognitive impairment (MoCA < 23; (Nasreddine et al., 2005))
Able to ambulate 200 m without personal assistance	Travelling for more than 2 months within the first 6 months of the intervention
	Unavailability for home visits or group training within 11 weeks of baseline measurement
	Residence in > 15km from city center
	Extreme hearing loss
	Current participation in another scientific trial

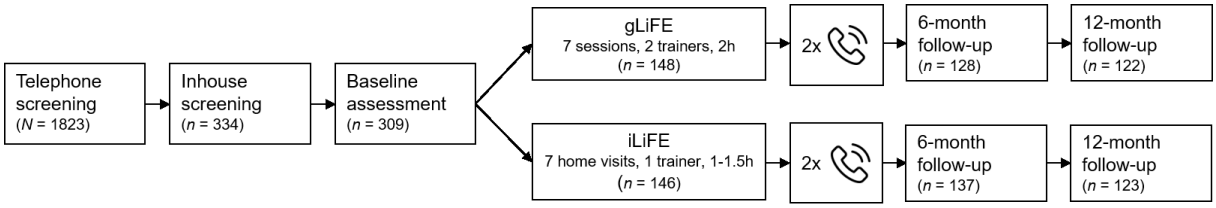
Note. A fall is defined as "an unexpected event in which the participant comes to rest on the ground, floor, or lower level" (Lamb et al., 2005); TUG = Timed Up and Go

At baseline assessment, participants filled out interviewer-supported questionnaires and their motor capacity was assessed (see below). Participants were equipped with an accelerometer and a fall calendar at the end of the baseline assessment. Participants then were randomly allocated to either LiFE or gLiFE. Both LiFE and gLiFE were delivered over the course of 11 weeks, followed by two booster phone calls 4 and 10 weeks after the last intervention session.

One trainer conducted LiFE at participants' homes, whereas gLiFE was delivered by two trainers at the study cite or in municipal buildings. Follow-up assessments took place 6 (± 2 weeks) and 12 months (± 2 weeks) after intervention start and were conducted by assessors blinded towards group allocation.

Figure 10

Flow Chart of the LiFE-is-LiFE Trial



Note. The participant numbers refer to the full sample, which was partly assessed in Heidelberg and Stuttgart.

The study had two primary outcomes. First, falls per physical activity unit were assessed, respecting the relationship between increased physical activity levels and resulting falls rate increases (see chapter 1.2.2). Falls were assessed using a monthly fall calendar on which location, date, time, injuries, and potential subsequent treatment related to the fall could be recorded. Additionally, falls incidences were followed up via telephone. Physical activity was measured for nine days using the activPAL4 micro (PAL Technologies Ltd., Glasgow, Scotland), an accelerometer with good reliability and validity scores which can be attached to participants' upper thigh (Grant et al., 2006; Ryan et al., 2006). The other primary outcome was cost-effectiveness, i.e., the proportion of the difference in costs and the difference in health effects in both LiFE and gLiFE. Costs were operationalized as in- and outpatient treatment, care, transportation, medication, and intervention costs such as labor and material costs. Health effects were operationalized via quality-adjusted life years based on the EQ-5D 5 L (Janssen et al., 2013).

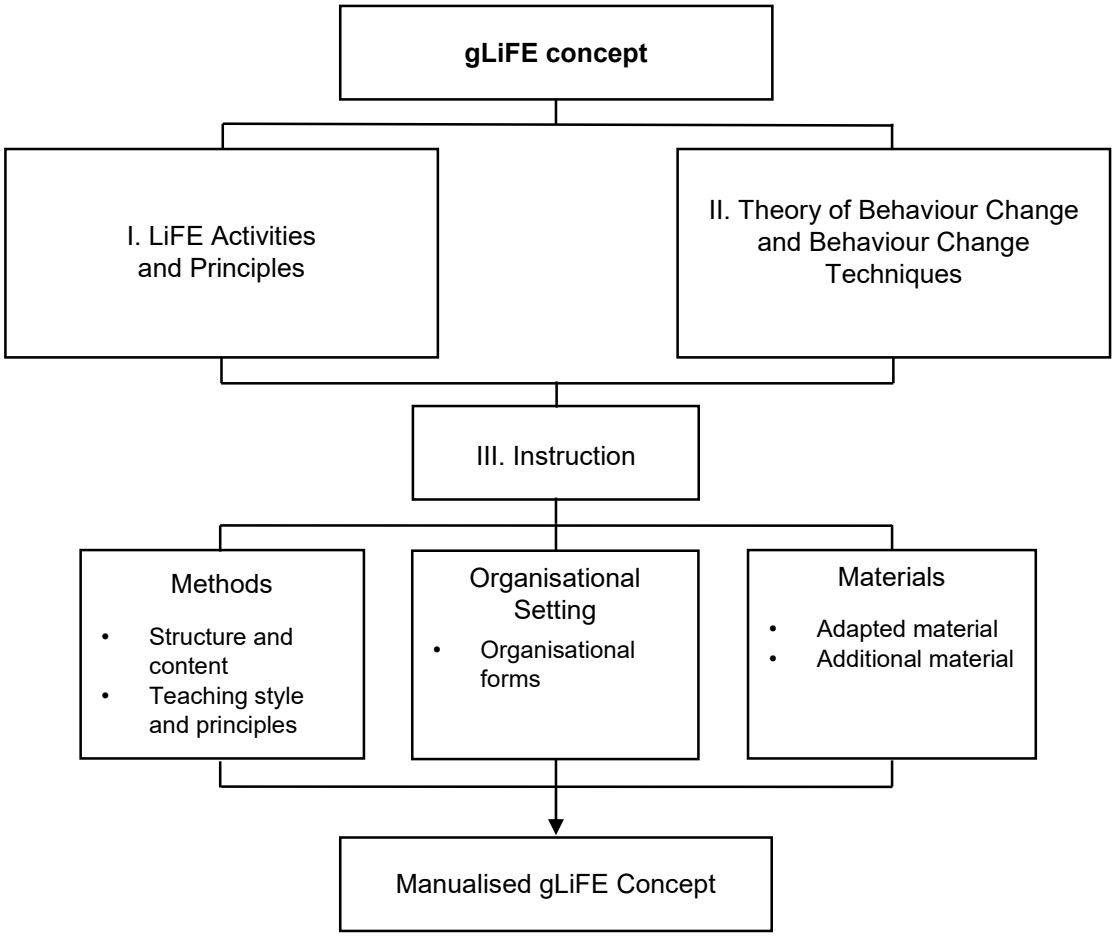
The following secondary outcomes were assessed in addition to physical activity, falls and cost-effectiveness: motor capacity (using the 7m gait speed test, 30-s Chair-Stand Test, and 8-level balance scale; Clemson et al., 2012; Jones et al., 1999), functional (dis-)ability (using the Late Life Function and Disability Instrument; Haley et al., 2002), adherence (using completion in terms of attendance of at least 75% of sessions, attendance in terms of percentage of sessions attended, and duration adherence measured by the Exercise Adherence Rating Scale; Hawley-Hague et al., 2016; Newman-Beinart et al., 2017), fear of falling (Short Falls Efficacy Scale-International; Kempen et al., 2008) and balance confidence (Activities-specific Balance Confidence Scale; Schott, 2008). The assessment of psychological variables will be presented in chapter 3.3.

3.3. Methods of this Dissertation Project

The current work is divided into the development and evaluation phase of gLiFE. During the development process, I modified the existing conceptual model of gLiFE by strengthening the focus on behavior change. The new conceptual gLiFE model is depicted in Figure 11.

Figure 11

The gLiFE Concept



Note. The second pillar *theory of behaviour change and behaviour change techniques* is novel to gLiFE and provides a theoretical underpinning using the HAPA, self-determination theory, and habit-formation theory as well as a conceptualization and description of gLiFE's components with the help of the BCTs.

Along the development process, preparatory work was conducted to examine the application of the HAPA with regard to older adults' walking duration as a specific surrogate of older adults' physical function (chapter 4.1). gLiFE's evaluation in comparison to LiFE along the guidelines for the development and evaluation of complex interventions (Craig et al., 2008; Moore et al., 2015), not only included analyses of gLiFE's effectiveness (chapter 4.4), but also participants' perceptions (chapter 4.3 and 4.5) and changes in psychological determinants of health behavior change such as motivational and volitional constructs or habit strength (chapter 4.6).

3.3.1. The gLiFE development process

Since gLiFE ought to be similarly effective, but less resource-intensive than LiFE (Jansen et al., 2018), the intervention format and content were kept as close to LiFE as possible. However, behavior change theory was applied in gLiFE to support participants' habit formation. In the development process of gLiFE, empirically established health psychological theories such as the HAPA (Schwarzer, 2008), the self-determination theory (R. M. Ryan & Deci, 2000), habit formation theory (Gardner & Lally, 2018), were applied, along with the behavior change technique (BCT) taxonomy (Michie, Ashford, et al., 2011). The targeted use of specific BCTs should help in the implementation of behavior change theory and its effective delivery. The selection of the BCTs was based on LiFE, experience reports from the LiFE-based previous study *PreventIT* (Taraldsen et al., 2019), and in consultation with important representatives of the LiFE program (including Lindy Clemson and Lena Fleig). We determined the specific implementation of the BCTs, meaning the time frame and materials used to implement the respective BCT in the LiFE program. The list of all included BCTs is provided in Table 2.

For example, in the previous format, the BCT 1.4. *Action planning* was implemented with just one question ("When, where and how do you perform the LiFE activities?"). In the newly designed gLiFE, the participants are instructed to precisely describe their exercise situation and LiFE exercise using specific if-then plans (implementation intentions; Gollwitzer, 1999) and thus to strengthen the cue-behavior association, e.g. "If I get a cup from the cupboard in the morning before breakfast, then I stand on tiptoe and hold on to the work surface". Another important BCT under the LiFE program is 7.1 *Cues*. For the concrete implementation, I designed a short theory unit (approx. 10 minutes) for gLiFE, in which the trainer first explains the difference between situation-related and object-related key stimuli. The participants should then collect various examples for each category together, e.g. cupboard as an object-related key stimulus and having breakfast as a situation-related key stimulus.

In addition, various materials were newly designed and produced to clarify the LiFE principles and LiFE exercises, e.g., laminated cards, posters or fabric panels. In addition to the participants' manual (Clemson et al., 2018), participants received a newly designed workbook, in which they could record their LiFE action plans and monitor their LiFE training.

A necessary step that went hand in hand with the conceptualization of gLiFE was creating a detailed manual for the delivery of the intervention sessions and booster phone calls, which did not exist for LiFE. This resulted in advantages with regard to the standardization of the intervention sessions between different trainers (i.e., intervention fidelity).

Table 2

BCTs Included in LiFE and gLiFE

BCT	Form of delivery individual setting (LiFE)	Adapted form of delivery group-based setting (gLiFE)	Underlying psychological determinant	Related theory	Used in LiFE	Used in gLiFE
1.1. Goal setting (behaviour)	Set the goal to perform a LiFE activity in a specific daily situation		Intention, competence	HAPA, SDT	x	x
1.2. Problem solving	Report about implementation of LiFE activities into daily habits at the beginning of each session. Find solutions for barriers	Exchanging experiences in the group	Coping planning, competence	HAPA, SDT	x	x
1.4. Action planning	Write down (self-chosen) implementation intentions into activity planner		Action planning, autonomy, Developing cue-behavior association	HAPA, SDT	x	x
1.5. Review behaviour goal(s)	Fine-tune action plans in discussion with trainer	Group discussion	Self-efficacy, competence	HAPA, SDT	x	x
2.2. Feedback on behaviour	Trainer gives feedback on movement execution of LiFE activities		Self-efficacy, competence	HAPA, SDT	x	x
2.3. Self-monitoring of behavior	Tick the box in activity planner in case of successful performance of action plan		Action control, competence	HAPA, SDT	x	x
2.7 Feedback on outcome(s) of behavior	Trainer acknowledges progress in movement execution during repetition of LiFE activities		Self-efficacy, competence	HAPA, SDT	x	x
3.1. Social support (unspecified)	Provided by trainers, e.g. praise, support in case of barriers (see 1.2.)	Provided by trainers and peers, scaffolding each other when practicing	Relatedness	SDT	x	x
4.1. Instruction on how to perform the behaviour	Demonstration of the LiFE activities (see 6.1.) by trainers and through LiFE manual		Self-efficacy, competence	SDT	x	x
4.2. Information about antecedents	Information about the situational context as a cue for habits		Developing cue-behavior association	Habit-formation theory	x	x
5.1. Information about health consequences	Positive consequences of physical activity and adaptation to training (upgrading)		Outcome expectancies	HAPA	x	x

6.1. Demonstration of the behaviour	Demonstration of the LiFE activities with simultaneous verbal description of correct movement execution by trainers		Self-efficacy, competence	HAPA, SDT	x	x
7.1. Prompts/cues	Identification of daily situations as cues for LiFE activities; session 2: theoretical unit on object-based and situation-based cues		Developing cue-behavior association	Habit-formation theory	x	x
8.1. Behavioural practice/rehearsal	Introduction of two new LiFE activities, their functionality and correct movement execution		Repeating behavior	Habit-formation theory	x	x
8.3. Habit formation	Repeating LiFE activities in stable contexts and thereby developing cue-behavior association		Repeating behavior, developing cue-behavior association	Habit-formation theory	x	x
8.7. Graded tasks	Knowledge on how to upgrade LiFE activities in case of progression or recommendation by trainers		Self-efficacy, competence	SDT	x	x
9.1. Credible source	Trainer (as a credible source) explains LiFE activities and principles as well as behavior change concept		Self-efficacy, competence	SDT	x	x
10.4. Social reward	Positive reinforcement in case of success by trainers	By trainers and peers	Relatedness	SDT	x	x
12.1. Restructuring the physical environment	Positioning cues for performing the LiFE activities at salient places or placing notes to remember the LiFE activities		Developing cue-behavior association	Habit-formation theory	x	x
15.1. Verbal persuasion about capability	Tell participants that they can succeed with integrating the LiFE activities into daily routines even when it seems challenging in the beginning		Self-efficacy, competence	HAPA, SDT	x	x
15.2. Mental rehearsal of successful performance		Visualizing movement execution in specific daily situation at home	Self-efficacy, competence	HAPA, SDT		x
15.3. Focus on past success	Praise by trainers in case of successes during the week		Self-efficacy (a)		x	x

Note. The numbers in front BCTs refer to the BCT taxonomy v1 (Michie, Ashford, et al., 2011); HAPA = health action process approach; SDT = self-determination theory.

Regarding the mode of delivery, gLiFE was designed to be taught in seven units over a period of 11 weeks, similar to LiFE. The first three units took place on a weekly basis. Starting from the fourth unit, the period between the units was extended to 2 weeks. The length of each unit was set to be approximately two hours in gLiFE. In contrast to the individual imparting of LiFE by a trained trainer, gLiFE was delivered to a group of eight to twelve participants by a team of trainers (a main and a co-trainer).

After an introductory session in which the participants get to know the LiFE principles and the first four exercises (tandem stand, tandem walk, getting up from the chair and squats), the similarly structured sessions 2-6 followed: They started with a repetition of the LiFE activities and a discussion of the experiences from the last week. Afterwards, a short theoretical unit on behavior change was led by the trainer and delivered in an interactive manner. Two to four new LiFE exercises were then introduced, which were then embedded in appropriate everyday situations. After the detailed action planning for the implementation of the LiFE activities, the participants were dismissed for the next exercise week(s). In the last session, all theoretical content and LiFE exercises were repeated again. It was intended to give the participants the last bit of help before they continue the LiFE exercises on their own.

Four and 10 weeks after the end of the intervention, two telephone calls were made in both intervention formats (gLiFE and iLiFE). In the approx. 45-minute talks, the participants were supported in maintaining or resuming the LiFE exercises. The focus was on finding possible solutions to existing difficulties and barriers to the implementation of the LiFE program.

3.3.2. Evaluation of gLiFE in comparison to LiFE

The evaluation of gLiFE also took place in the course of the larger LiFE-is-LiFE trial. Theory-based psychological determinants of behavior change were examined using questionnaire data. Table 3 provides an overview of the relevant questionnaires, measurement points, and response scales. Mainly, the questionnaires were applied at baseline, 6-month, and 12-month follow-up, interviewer-supported. Selected assessments such as intention, action and coping planning, action control, and habit strength also were applied at the last intervention session and at the booster phone calls. More measurement points enable detailed analyses on the dynamics of psychological determinants of behavior change.

Data analysis was conducted based on both quantitative and qualitative data. Quantitative data analysis was performed using both per-protocol and intention-to-treat analyses, the latter one using a dataset with imputed missing data. A one-sided Pearson’s chi-square test was used to determine non-inferiority. Secondary outcomes were analyzed using generalized linear models with repeated measures. Qualitative data was analyzed using qualitative content analyses by Mayring (2014).

Furthermore, structural equation modeling (SEM) and linear mixed models (LMM) were applied. SEM allows the test of the relationships between multiple, pre-defined theoretical constructs (Kaplan, 2001). The linear equations between variables can be defined between both observed variables and so-called latent, unobservable variables (constructs) which are assumed to be free of measurement error (Sinharay, 2010). The fit of this model to the data was determined by using estimation algorithms such as maximum-likelihood estimation. Different fit indices were then used to determine how well the data fits the specified model. Most commonly, the Comparative Fit Index (CFI), the Tucker-Lewis-Index (TLI), the root-mean-square error of approximation (RMSEA) and its 90% CI, and the standardized root-mean-squared residual (SRMR) were used. High CFI (>.90) and TLI values (>0.95), and low RMSEA (<.06) and SRMR (>.09) values indicate good model fit (Hu & Bentler, 1999; Steiger, 2007). The RMSEA 90% CI marks the precision of the RMSEA value; a small range and the proximity of the lower bound to zero suggest a small error (Curran et al., 2003). Furthermore, the Akaike's Information Criterion (AIC) and the Bayesian Information Criterion (BIC) were used to compare models , with lower AIC and BIC values indicating superiority of one model over another. LMM is an extension of linear regression models which can be used when data points share variance, for example in repeated measures designs. In comparison to a repeated measures analysis of variance (ANOVA), LMM enables better treatment of missing data and operates with fewer assumptions.

Table 3

Overview Over the Psychosocial Constructs Assessed in the Life-is-Life Trial

Theory	Construct	Questionnaire	Reference	Number of items	Measurement points	Response scale	Example
HAPA	Self-efficacy	HAPA-based	Sniehotta, Scholz, & Schwarzer (2005)	6	Baseline 6m follow-up 12m follow-up	0 (*I totally disagree*) to 6 (*I totally agree*)	*I am sure that I can integrate more physical activity into my daily routines.*
	Outcome expectancies	HAPA-based	Sniehotta, Scholz, & Schwarzer (2005)	2	Baseline 6m follow-up 12m follow-up	0 (*I totally disagree*) to 6 (*I totally agree*)	*If I practice LiFE regularly, then I can prevent falls.*
	Risk perception	HAPA-based	Sniehotta, Scholz, & Schwarzer (2005)	3	Baseline 6m follow-up 12m follow-up	1 (*way below average*) to 5 (*way above average*)	*Compared to other people of my age and sex, my chances of falling are …*
	Intention	HAPA-based	Sniehotta, Scholz, & Schwarzer (2005)	2	Baseline Session 7 Booster call 1 & 2 6m follow-up 12m follow-up	0 (*I totally disagree*) to 6 (*I totally agree*)	*I intend to live an active lifestyle.*
	Action planning	HAPA-based	Sniehotta, Scholz, & Schwarzer (2005)	3	Baseline Session 7 Booster call 1 & 2 6m follow-up 12m follow-up	0 (*I totally disagree*) to 6 (*I totally agree*)	*In the past 4 weeks, I have made a detailed plan how I can integrate more physical activity into my daily life.*

	Coping planning	HAPA-based	Sniehotta, Scholz, & Schwarzer (2005)	3	Baseline Session 7 Booster call 1 & 2 6m follow-up 12m follow-up	0 (*I totally disagree*) to 6 (*I totally agree*)	*In the past 4 weeks, I have made a detailed plan how I can be physically active even if something else comes up.*
	Action control	HAPA-based	Sniehotta, Scholz, & Schwarzer (2005)	2	Baseline Session 7 Booster call 1 & 2 6m follow-up 12m follow-up	0 (*I totally disagree*) to 6 (*I totally agree*)	*In the past 4 weeks, I thoroughly took care of doing my LiFE activities as I planned them.*
SDT	Fulfillment of psychological needs	Psychological Need Satisfaction in Exercise Scale	Rackow et al. (2013)	12	Session 2 Session 7	0 (*I totally disagree*) to 7 (*I totally agree*)	*I feel I have the opportunity to make choices with respect to the LiFE program.*
	Motivation quality*	Behavioural Regulation in Exercise Questionnaire 3	Markland & Tobin (2004)	24	Baseline 6m follow-up 12m follow-up	0 (*I totally disagree*) to 4 (*I totally agree*)	*I am physically active because it is fun*
Habit formation theory	Habit strength	Self-Report Behavioural Automaticity Index	Gardner et al. (2012)	4	Baseline Session 7 Booster call 1 & 2 6m follow-up 12m follow-up	0 (*I totally disagree*) to 7 (*I totally agree*)	*The LiFE activities are something I do automatically.*

Note. SDT = self-determination theory; * motivation quality includes intrinsic motivation, among others

3.4. The LiFE-is-LiFE Sample

Since all analyses conducted in the course of this dissertation project are based on data from the LiFE-is-LiFE trial, the sample is described once in detail. In the publication summaries (chapter 4.1 – 4.6), it will only be mentioned which cases were included in the respective analyses. In total, 1,823 older adults were screened for eligibility and *N* = 309 participants were assessed at baseline. Baseline characteristics are displayed in Table 4. After randomization, *n* = 147 participants started the LiFE and *n* = 148 participants started the gLiFE intervention. At the 6-month follow-up, *n* = 137 LiFE, and *n* = 128 gLiFE participants were assessed. At the 12-month follow-up, *n* = 123 and *n* = 122 were available for assessment (Figure 10).

Table 4

Participant Characteristics at Baseline

N (mean ± SD)	All *N* = 309	LiFE *n* = 156	gLiFE *n* = 153
Age, years	78.8 ± 5.3	78.8 ± 5.2	78.7 ± 5.4
Sex, *n* (%) female	227 (73.5)	115 (73.7)	112 (73.2)
BMI [kg/m²]	27.2 ± 4.9	27.7 ± 5.0	26.8 ± 4.7
No. of medications	4.9 ± 3.4	5.0 ± 3.3	4.8 ± 3.4
No. of comorbidities	2.5 ± 1.6	2.5 ± 1.5	2.5 ± 1.6
MoCA Score	26.0 ± 2.0	26.1 ± 2.0	25.9 ± 2.0
No. of steps/day	5,659 ± 2,919	5,778 ± 3,009	5,538 ± 2,828
No. of falls p.p. in past 6 months	0.66 ± 1.1	0.66 ± 1.1	0.65 ± 1.1
% of fallers in past 6 months	126 (40.8)	63 (40.4)	63 (41.2)
30 sec Chair Stand	9.1 ± 3.9	9.2 ± 3.8	9.0 ± 3.3
8 Level Balance Scale	4.3 ± 1.5	4.2 ± 1.5	4.4 ± 1.4
Short FES-I	10.4 ± 3.0	10.4 ± 3.1	10.3 ± 3.0
ABC Scale	75.3 ± 16.8	75.0 ± 17.6	75.5 ± 16.9

Note. ABC Scale: Activities-specific Balance Confidence Scale; BMI: body mass index; CI: confidence interval; FES-I: Falls Efficacy Scale International; ITT: intention-to-treat; MoCA: Montreal Cognitive Assessment; No.: Number; p.p.: per person; SD: standard deviation

The participants in the LiFE-is-LiFE trial (*N* = 309) were 78.8 years old on average (range 70-94 years). The majority of participants were female (73.5%). Regarding falls, 40.8% of participants reported to have fallen within the 6 months prior to the study. Heterogeneity between participants existed regarding years of education (*M* = 13.8 years, *SD* = 4.00, range = 3–9).

Regarding higher education, 35% of participants had a high school degree and 23% had a university degree. Almost half of the participants (45%) were living in a long-term relationship or marriage, 36% were widowed,13% were separated or divorced, and 6% were unmarried.

4. Publication Summaries

4.1. Publication I: Applying Social Cognition Models to Explain Walking Duration in Older Adults: The Role of Intrinsic Motivation

Sarah Labudek, Lena Fleig, Carl-Philipp Jansen, Franziska Kramer-Gmeiner, Corinna Nerz, Clemens Becker, Jochen Klenk, & Michael Schwenk (2021). *Journal of Aging and Physical Activity, 29*(5), 744-752. https://doi.org/10.1123/japa.2020-0296

Background

Older adults' health behavior and individual lifestyle factors, for example physical activity, play a major role for healthy aging (Daskalopoulou et al., 2017). However, poor health status often impedes older adults from engaging in regular physical activity (Mannucci & Nobili, 2014), which negatively affects their motivation to be more physically active (Gellert et al., 2015). Examining the modifiable, psychological factors which predict walking behavior as a functional and relatively safe type of physical activity could foster theoretical advances in the modeling of walking as a health behavior and promote the design of health behavior interventions.

The health action process approach (HAPA; Schwarzer, 2008) is a health behavior change model which entails self-efficacy and planning as two main predictors to bridge the so-called *intention-behavior gap*. Intention in the HAPA is solely assessed by motivation quantity, whereas the self-determination theory describes motivation quality, i.e., why older adults are motivated to engage in a certain health behavior such as physical activity (R. M. Ryan & Deci, 2000). Intrinsic motivation, e.g., experiencing fun and joy while being physically active, could be an important motivation quality for older adults because of their orientation towards emotionally meaningful goals (Carstensen et al., 2003; Mikels et al., 2014).

In this study, the HAPA was applied to older adults' walking duration. It was then tested whether the extension of the HAPA by intrinsic motivation would add predictive value to the HAPA.

Methods

Baseline data from the LiFE-is-LiFE trial (Jansen et al., 2018) was used for the analyses. At baseline assessment, trained interviewers administered Likert-scaled questionnaires for the HAPA (self-efficacy, risk perception, outcome expectancies, intention, action planning, and coping planning) and self-determination theory (intrinsic motivation). To measure walking duration, participants wore the activPAL4^{TM} for 7 full consecutive days after baseline assessment. In the analyses, walking duration ≥ 3 metabolic equivalents of task (METs) was used, so that only more intensive and longer periods of walking were considered.

For data analyses, two structural equation models (SEM) were specified using the lavaan package in R. Five and six latent variables were included in the models for the HAPA and the extended model, respectively. Intrinsic motivation was included as a parallel mediator to intention. Walking duration was included as a manifest variable and age, sex, BMI, living situation and fear of falling were included as covariates in both models. Model fit was determined using the CFI, TLI, RMSEA and its 90% CI and the SRMR. Fits of both models were compared using the AIC, BIC, and variance explained in walking duration.

Results

Data of all N = 309 participants (74% female) who completed the baseline assessment was included in the analyses. The SEM which tested the HAPA showed a good fit to the data (CFI = .96, TLI = 0.94, RMSEA = .04 [CI = 0.02–0.05], SRMR = .06); the variance explained in walking duration was R^2 = .14. Planning was not significantly related to walking duration (β = .06, p = .256), however, age, BMI, living situation, and fear of falling showed negative associations with walking duration, indicating that participants who were older, had a higher BMI and fear of falling, and participants who lived together with someone had shorter walking durations.

For the extended model, the fit indices were slightly lower (CFI = .95, TLI = 0.94, RMSEA = .04, 90% CI [0.03–0.05], SRMR = .06); the variance explained in walking duration was R^2 = .17. Intrinsic motivation showed significant associations with risk perception intention (β = .29, p < .001), planning (β = .17, p = .036), and walking duration (β = .21, p < .001). When comparing the two models, the HAPA showed lower AIC and BIC values, indicating a better model fit. However, the variance explained of walking duration was higher in the extended model.

Discussion

According to the increased importance of experiencing positive emotions in older age (Carstensen et al., 2003), the HAPA was extended by intrinsic motivation and applied to walking duration as an age-appropriate type of physical activity for community-dwelling older adults at risk of falling. The findings show that although the HAPA fit the data better than the extended model, intrinsic motivation emerged as the only significant psychological variable which was significantly related to walking duration. The extension of the HAPA by intrinsic motivation led to an increase in the variance explained in walking duration by 3%, indicating that feelings of intrinsic motivation such as having fun or experiencing joy contribute a small proportion to explain walking duration of older adults. Two major limitations are the short time lag between the assessment of social-cognitive predictors and walking duration and the restricted sample in terms of high levels of motivation, which limits the generalizability of the present results. In summary, this study showed that HAPA-based psychological determinants were not associated with older adults' walking duration. Intrinsic motivation revealed itself to be the only factor which was significantly related to walking duration, which has implications for research and

practice. Researchers should work towards combining factors of different theories and applying them to relevant target populations and behaviors. A practical implication would be that walking interventions for older adults should focus on evoking feelings of fun and enjoyment.

4.2. Publication II: Development of a Conceptual Framework for a Group-Based Format of the Lifestyle-integrated Functional Exercise (gLiFE) Program and its Initial Feasibility Testing

Franziska Kramer*, Sarah Labudek*, Carl-Philipp Jansen, Corinna Nerz, Lena Fleig, Lindy Clemson, Clemens Becker, & Michael Schwenk (2020). *Pilot and Feasibility Studies,* 6:6. https://doi.org/10.1186/s40814-019-0539-x

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Background

The Lifestyle-integrated Functional Exercise (LiFE) program is a fall prevention and physical activity promotion program for community-dwelling older adults at risk of falling. Unlike structured balance and strength training programs, LiFE aims to integrate functional balance and strength activities into daily routines such as household chores. From a behavior change perspective, habit formation and autonomy support of participants are core determinants of the program. In a large RCT, LiFE was shown to be effective in terms of fall reduction, functional outcomes (e.g., balance capacity), and adherence compared to both structured training and a sham intervention group (Clemson et al., 2012). A disadvantage of LiFE is its delivery format: seven individual home visits by trainers to support participants in tailoring their individual LiFE routines are highly resource-intensive and thus unlikely to be implemented on a large scale. A promising alternative would be delivering LiFE in a group format. Three studies have made attempts at designing a group-based LiFE format (Fleig, McAllister, et al., 2016; Gibbs et al., 2015, 2019; Li et al., 2018). However, none of these programs was explicitly designed for the purpose of large-scale implementation. This study presents the development of a hypothetically resource-saving group-based LiFE (gLiFE) format and its initial feasibility testing. To boost gLiFE's effectiveness, the theoretical basis for behavior change and habit formation was refined.

Part I: Conceptual gLiFE Framework

The gLiFE concept is based on existing LiFE concepts as well as theories and methods on group learning. In the development process, an interdisciplinary team of experts used the MRC guidelines for the design of complex interventions (Craig et al., 2008). gLiFE consists of three pillars: the activities and LiFE principles for balance and strength training (pillar I), theories and techniques on behavior change (pillar II), and instruction (pillar III; Figure 11). The theoretical underpinning of LiFE consists of existing LiFE concepts (Clemson & Munro, 2015; Fleig, McAllister, et al., 2016), habit formation theory (Gardner & Lally, 2018; Lally & Gardner, 2013),

the HAPA (Schwarzer, 2008), and the self-determination theory (R. M. Ryan & Deci, 2000). Regarding instruction (pillar III), gLiFE is taught by two trainers to a group of 8-12 participants in seven sessions. Additionally, the methods, organizational setting, and materials used to deliver gLiFE were specified in pillar III. For example, group discussions on topics such as potential situational contexts to practice LiFE were included to increase group interactions. For fostering habit formation, so-called *implementation intentions* (Gollwitzer, 1999) were used as a specific planning strategy to help build associations between the specific situational context and a particular LiFE activity. The gLiFE manual (in German language) contains a detailed description of each session.

Part II: Feasibility Testing

Methods

The proof-of-concept was tested in a single-group feasibility study (clinicaltrials.gov, identifier: NCT03412123) using a mixed-method approach. Likert-scaled questionnaires on the evaluation of gLiFE assessing perceived safety and adverse events, adherence, and acceptability were applied, and a semi-structured focus group interview was conducted. Additionally, social-cognitive measures on behavior change, i.e., intention, self-determined exercise motivation, action and coping planning, action control, and habit strength, were applied at baseline and at the last intervention session. We analyzed descriptive values using medians and interquartile ranges (IQRs). The recording of the focus group interview was transcribed verbatim and analyzed using an inductive qualitative content analysis.

Results

Six participants (median = 72.8 years old, IQR = 2.8, 5 female) completed the intervention. On average, five of the six participants attended each session. The delivery of gLiFE took place as planned. Trainers perceived the setting and materials as feasible and safe, although simultaneously assessing training levels of all participants was challenging. Participants stated to feel *very safe* while performing the LiFE activities in the group and rated gLiFE's acceptability as *very good*. Participants rated gLiFE as *helpful* concerning balance and strength improvement and the LiFE activities to be *rather easy* to integrate into daily life. At the end of the intervention, participants reported to have implemented 9.5 (IQR = 4.0) LiFE activities and practiced on 5.2 (IQR = 2.1) days per week.

Five participants took part in the focus group discussion. Three categories emerged from the qualitative content analysis: format (e.g., "good systematic structure"), implementation of activities (e.g., "planning and the identification of cues were a helpful strategy"), and perceived intervention effects (e.g., "feeling much safer while walking on the street").

Exploratory measures on psychological determinants of behavior change revealed high and stable values of intention, and higher values of intrinsic motivation, action and coping planning, and habit strength post intervention, whereas levels of action control decreased.

Discussion

This study presented the successful development and feasibility testing of gLiFE, a group-based LiFE concept designed for large-scale implementation within the (German) public health system. gLiFE offers both a profound theoretical basis and detailed instructions for delivery. By implementing interactive elements, the presence of peers is explicitly used as the unique feature of gLiFE in comparison to LiFE. The theoretical framework regarding structure and content was redefined to boost gLiFE's long-term effectiveness on the basis of current theoretical advances and research evidence. The gLiFE manual ensures standardized dissemination and fidelity of delivery in the LiFE-is-LiFE trial.

Findings from the feasibility testing suggest gLiFE to be both feasible and well-accepted by participants. The fact that no adverse events were reported supports that participants understood the recommendations and practiced LiFE safely, including in their homes. Participants' high implementation (75%) and attendance (83%) rates suggest additional, indirect markers for gLiFE's acceptance. Qualitative feasibility measures supported quantitative findings; participants stated their positive attitudes towards the gLiFE format and their perceived positive results regarding physical function, well-being, and habit formation. One problematic aspect is that some participants did not perform the LiFE activities in their pre-specified daily situations, but rather decided spontaneously when and where to do them, which might hamper behavioral maintenance and habit formation (Gardner, 2015; Neal et al., 2006). However, on the basis of the exploratory measures of behavior change, participants reported higher levels of habit strength post intervention. Higher levels of action planning indicate the successful use of implementation intentions, although participants reported the handling of the activity planner to be tedious.

In summary, this paper presented the theory-based, standardized, and manualized gLiFE concept, which was feasible and accepted in the target group of fall-prone older adults. It can be assumed that LiFE has the potential for large-scale implementation, but future studies will need to assess cost-effectiveness in comparison to LiFE to prove that gLiFE is a cost-effective alternative to home visits.

4.3. Publication III: Group or Individual Lifestyle-integrated Functional Exercise (LiFE)? A Qualitative Analysis of Acceptability

Leah Reicherzer, Franziska Kramer-Gmeiner, Sarah Labudek, Carl-Philipp Jansen, Corinna Nerz, Malin J. Nystrand, Clemens Becker, Lindy Clemson, & Michael Schwenk (2021). *BMC Geriatrics, 21:93.* https://doi.org/10.1186/s12877-020-01991-0

Background

High *acceptability* of fall prevention intervention is a prerequisite to counterbalance the rising fall incidence expected in older adults in the coming years (WHO, 2015). Acceptability of interventions has been shown to determine long-term success of health behavior interventions (Michie, van Stralen, et al., 2011). Acceptability is a multi-faceted construct and refers to participants' attitudes towards the perceived appropriateness of an intervention (Sekhon et al., 2017). Components of acceptability range from more intervention-related aspects such as intervention coherence and ethicality to more person-related aspects such as affective attitudes, opportunity costs, perceived effectiveness, and self-efficacy. No large-scale examination of LiFE's acceptability has been conducted so far. This study presents the evaluation of participants' attitudes towards the LiFE program and its newly developed group-based format (gLiFE).

Methods

For this qualitative study, a subsample from the LiFE-is-LiFE trial (Jansen et al., 2018) was drawn using purposeful sampling (Palinkas et al., 2015) after the 6-month follow-up. For this subsample, 30 participants (22 women, 8 men; M_{age} = 78.8; range 70–96 years; n_{gLiFE} = 15; n_{LiFE}= 15) with varying age, gender and levels of habit strength were selected to create a diverse sample.

The semi-structured interview guide consisted of 14 main questions on the two LiFE formats. Two focus group discussions were conducted per format at each study cite, one for LiFE ($n_{Stuttgart}$ = 7, $n_{Heidelberg}$ = 8), one for gLiFE ($n_{Stuttgart}$= 8, $n_{Heidelberg}$ = 7). The focus group discussions were audio-recorded and transcribed following the guidelines by Kuckartz (2014). A qualitative content analysis using inductive category formation according to Mayring (2014) was performed. Coding was performed using NVivo 12 (QRS International, Australia). Researchers conducted category formation as close to the material as possible and only the material relevant to the facets of acceptability (expression of affective attitudes towards the programs, burden, coherence, perceived effectiveness, and self-efficacy), as well as overall evaluation of the two LiFE formats were used. In a last step, categories were sorted into umbrella themes and contents were contrasted by group. Statements are marked with "o" and "g" for LiFE and gLiFE, gender ("F" for female or "M" for male) and age.

Results

Five umbrella themes emerged from the material: *program overall*, *trainer support*, *intervention content*, *intervention format*, and *changing behavior*. Both LiFE and gLiFE participants were positive about the program overall but found the paperwork "quite annoying" (gF70). Participants in both formats liked the trainer support: gLiFE participants reported that they "never had to feel embarrassed" (gF72) when they could not perform a LiFE activity, whereas LiFE participants stressed the positive personality of trainers and appreciated the shared personal time ("I liked that you could talk to them about personal stuff", oF74). Regarding the intervention content, participants valued the "well balanced and instructive" (gM82) nature of both LiFE and gLiFE. Most participants were satisfied with the programs' intensity, but some participants wished for more strength training "to guarantee stability" (oM83) and found some LiFE activities "not natural" (gF73) or "silly" (oM80). Some gLiFE participants stated that the peers are motivating ("you want to keep up with the others", gF88), comforting ("all face difficulties with walking and climbing stairs", gF91) and that interaction was fun, although some "never felt a sense of companionship" (gF84). LiFE participants liked the home visits and the flexible scheduling and considered the booster phone calls as "quite good" (oF72) to help with the transition from supervised to independent training. When asked about the other intervention format, some LiFE participants stated that they would have preferred being in a group with peers and criticized that the notably younger trainers "can't really understand how we feel" (oF82). gLiFE participants stressed that one home visit to identify suitable spots to practice at home would be "an enhancement" (oF84) as some plans formed in the group sessions were not applicable to the home setting. Regarding changing behavior, both LiFE and gLiFE participants reported that the LiFE activities "became a habit" (gF82) and emphasized that situational cues reminded them to integrate the LiFE activities. Both LiFE and gLiFE participants reported an improved physical function or mobility or increased activity levels. Most LiFE and gLiFE participants were positive about their ability to perform the LiFE activities, whereas LiFE participants were concerned about their LiFE practice fading out without regular trainer support.

Discussion

This study compared acceptability of LiFE and gLiFE. Both LiFE and gLiFE participants found the two formats acceptable, indicating the suitability of both formats for the target group. Our findings on the importance of individual trainer support, which was explicitly stressed in LiFE, are in line with previous studies (Keay et al., 2017; Lindelöf et al., 2017). Regarding self-efficacy as an important factor for intervention acceptability (Sekhon et al., 2017), both LiFE and gLiFE participants stated to have built confidence in the ability to perform and maintain the LiFE activities. Participants liked the structure, including the repetition of activities in the beginning, indicating that the modifications of the LiFE program when developing gLiFE were well-received. Since some LiFE activities were perceived as too artificial, future studies could

conduct an in-depth analysis of each LiFE activity's feasibility. Generally, participants found the effort to take part in LiFE and gLiFE to be appropriate, but paperwork needed to be simplified. Trainers could focus more on teaching and applying the principle of upgrading to increase intensity levels. The fact that not all participants perceived motivational benefits of having social support through peers in gLiFE might be due to the lack of a shared goal, which is assumed to foster group cohesion (Estabrooks & Carron, 1999). gLiFE participants proposed a single home visit to foster the implementation of activities, but this would reduce cost-effectiveness and could hamper large-scale implementability.

In summary, gLiFE and LiFE were both perceived as acceptable and the unique features of each format were acknowledged: gLiFE stands out with its opportunity to interact with peers and might thereby influence participants' affective attitudes and motivation; LiFE is attractive because trainers can provide individual support at participants' homes which might promote implementation of the LiFE activities on a more individual level. Based on the results of the study, both LiFE and gLiFE are acceptable intervention formats from the participants' perspective.

4.4. Publication IV: Lifestyle-integrated Functional Exercise to Prevent Falls and Promote Physical Activity: Results From the LiFE-is-LiFE Randomized Non-Inferiority Trial

Carl-Philipp Jansen, Corinna Nerz, Sarah Labudek, Sophie Gottschalk, Franziska Kramer-Gmeiner, Jochen Klenk, Judith Dams, Hans-Helmut König, Lindy Clemson, Clemens Becker, & Michael Schwenk (2021). *International Journal of Behavioral Nutrition and Physical Activity, 18*(1), 1–12. https://doi.org/10.1186/s12966-021-01190-z

Background

LiFE's delivery format – seven individual home visits – is resource-intensive and might pose a high burden for large-scale implementation into health care systems. Hence, the aim of this study was to compare the newly developed group-based LiFE format (Kramer et al., 2020) against the original LiFE format. The hypotheses that a) gLiFE is not less efficacious than LiFE regarding the reduction of activity-adjusted falls incidence, and that b) gLiFE is less costly than LiFE were tested in a non-inferiority trial. gLiFE's non-inferiority would be confirmed if the treatment effect lies within a pre-defined non-inferiority margin (Piaggio et al., 2010).

Methods

The LiFE-is-LiFE trial (clinicaltrials.gov, NCT03462654) was a single-blinded, multi-center, randomized non-inferiority trial. Due to the onset of the COVID-19 pandemic, the 6-month instead of the 12-month data was used for the analyses.

To determine activity-adjusted fall incidence (IRR), PA was measured using activPAL4™ micro accelerometers (PAL Technologies Ltd., Glasgow, Scotland) for 7 full days. PA was operationalized as mean steps/day. Falls were recorded by a monthly falls calendar. Number of falls and fall rate per (half) person year were used to describe fall incidence, among others. Intervention costs were determined as costs per participant for each format (LiFE/gLiFE) by taking material costs, travel expenses and room rent into account. Furthermore, intervention costs were calculated under a "real world" scenario.

Multiple imputations for missing values (0-17%) were performed using multiple imputation by chained equations (MICE) with predictive mean matching. Researchers also carried out intention-to-treat (ITT) and per-protocol (PP) analyses to examine robustness of the findings. Binomial regression was applied to compare IRRs of falls between gLiFE and LiFE with log-transformed values for the combined endpoint (falls per physical activity unit). Non-inferiority was indicated by the upper limit of the two-sided 95% CI for gLiFE remaining below the non-inferiority margin of 20% (IRR = 1.20).

Results

After baseline assessment, *N* = 309 participants were randomized in LiFE (*n* = 156) and gLiFE (*n* = 153). The mean age of the sample was 78.8 (± 5.3) years, and the majority of participants were female (73.5%). At the 6-month follow-up, 44 participants (14.2%) had dropped out of the study.

Regarding the combined endpoint, baseline and 6-month follow-up IRRs of gLiFE for the PP analysis were 1.27 (PP; 95% CI:0.80; 2.03) and 1.18 (ITT; 95% CI: 0.75; 1.84) at 6-month follow-up. Thus, non-inferiority was inconclusive because the upper CI crossed the pre-defined 20% margin. This indicates that the risk of experiencing a fall was higher for gLiFE participants, although the difference in IRRs between LiFE and gLiFE was not statistically significant. The average intervention costs per participant amounted to €350.10 for LiFE and €229.93 for gLiFE per participant, a difference of €120,17. Considering real world assumptions, this difference increased to €211.5, with €332.08 per LiFE participant and €120.58 per gLiFE participant.

Secondary analysis revealed that both LiFE and gLiFE participants increased their number of steps from baseline to 6-month follow-up, with significantly larger increases (p = .007) for gLiFE participants (change in steps/day 1,266 ± 213 [PP]; 1,309 ± 225 [ITT]) compared to LiFE participants (change in steps/day 386 ± 227 [PP]; 465 ± 257 [ITT]). For LiFE, the incidence of falls per half person year was 0.30 (SE 0.05) compared to 0.40 (SE 0.06) in gLiFE, according to ITT analysis (PP LiFE: 0.30, SE 0.05; gLiFE: 0.41, SE 0.06). The incidence of number of falls per half person year decreased from baseline to 6-month follow up about 55% in LiFE (0.66 to 0.30) and 37% (0.65 to0.41) in gLiFE (ITT).

Discussion

This study investigated whether the newly developed gLiFE format was non-inferior to the individually delivered LiFE format regarding activity-adjusted falls incidence and whether gLiFE was less costly than LiFE.

The non-inferiority testing of the activity-adjusted falls incidence was inconclusive. One potential explanation could be that the usage of 6-month instead of 12-month follow-up data might have led to a higher random error which might have biased the results. Another explanation could be that LiFE participants had closer and more direct supervision compared to gLiFE participants, which could have led to the higher adherence rates that eventually translated into a lower IRR. Nevertheless, both LiFE and gLiFE participants reduced their incidence of falls to 55% and 37%, respectively, which is greater than in the reference trial (31%) by Clemson et al. (2012). The fact that gLiFE was less costly than LiFE with simultaneously reducing falls underlines gLiFE's attractiveness for potential payers.

gLiFE showed a 23% increase in mean steps per day compared to 7% in LiFE. An increase of 1000 steps/day as induced by gLiFE has been associated with a decreased risk for all-cause mortality (Hall et al., 2020).

Limitations of the current study are that data from the 12-month follow-up, to which the trial was originally powered, could not be considered due to the onset of the COVID-19 pandemic. Furthermore, the falls assessment pre-baseline was retrospective, which hampers comparability to the data from the falls calendar assessed within the study period (Lamb et al., 2005). Lastly, the study sample deviated from the participants in the reference trial in terms of age, gender, and falls rate. Given that there was no control group, the findings of this study must be interpreted with caution.

In summary, both intervention formats have different advantages which promote their potential: LiFE seems better regarding the reduction of activity-adjusted falls incidence, whereas gLiFE was superior in promoting physical activity, and it was less costly. Older adults should be able to decide between both formats depending on their personal needs and capabilities.

4.5. Publication V: Participants' Evaluation of the Individual and Group-Based Life Program: Results From the LiFE-is-LiFE Trial

Melissa J. Wolf, Sarah Labudek, Christoph Endress, Carl-Philipp Jansen, Corinna Nerz, Clemens Becker, Lindy Clemson, & Michael Schwenk (submitted).

Introduction

Low levels of physical activity and high fall rate in older adults have hazardous consequences on the individual and societal level (Dallmeyer et al., 2017; Daskalopoulou et al., 2017). The LiFE intervention (Clemson et al., 2012) is proposed to tackle many reported barriers for physical activity such as time constraints or insufficient motivation by providing a habit-based, lifestyle-integrated approach which can be performed with low motivational effort and incidentally. A group-based version of LiFE (gLiFE) was recently tested against the original format. Both LiFE (-55%) and gLiFE (-37%) effectively reduced falls and promoted physical activity, with gLiFE participants showing significantly greater increases in steps/day at 6-month follow-up. The aim of this study was to complement these findings by adding the participants' perspective. To do so, participants' experiences were evaluated within the individual and group-based format regarding a) overall evaluation, b) perceived outcomes, c) delivery, and d) materials and content, including a comparison of long-term changes and differences.

Methods

The evaluation of participants' perspectives on LiFE and gLiFE reported in this study was performed using a 6-point Likert-scaled questionnaire at 6-month follow-up (T1) and 12-month follow-up (T2). The questionnaire was developed based on an acceptability questionnaire for LiFE in young seniors (Schwenk et al., 2019) and contained 23 items which were divided into the following categories: a) overall evaluation, b) perceived outcomes, c) delivery format, and d) materials and contents. The questionnaires were distributed via mail and followed up via telephone in cases of missing or unclear information. Statistical analyses were performed using descriptive statistics (Median and IQR), as well as Mann-Whitney-*U*, and Wilcoxon signed-rank test to compare groups and differences over time, respectively. In case of significant results, effect sizes were calculated using Pearson's correlation coefficient *r*.

Results

In total, data from n_{LiFE} = 126 and n_{gLiFE} =126 participants were included in the analysis for T1 and n_{LiFE} = 120 and n_{gLiFE} =120 for T2. Overall, the evaluation of both LiFE and gLiFE was good, indicated by medians ranging from 4 to 6 and low IQRs of mostly 1. Both LiFE and gLiFE participants rated the formats rather similarly, indicated by significant differences in only one (4.35%) of the 23 items at both 6-month and 12-month follow-up. Apart from the large consensus of LiFE and gLiFE participants, only one significant difference between formats was found

at 6-month follow-up. LiFE participants, as opposed to gLiFE participants, rated the helpfulness of implementation intentions (if-then plans for the context-dependent performance of the LiFE activities) to be higher (category materials and contents; U = 6.216, p = .002, n = 251, r = .19).

At 12 months, few deviations from the results at the 6-month follow up emerged, indicating that participants' evaluations stayed quite stable over time. LiFE participants reported higher levels of satisfaction with improvements in strength than gLiFE participants (category perceived outcomes; U = 5.563, p < .001, n = 120, r = .21). Additionally, LiFE participants perceived the integrability of the LiFE activities significantly lower than at 6-month (category overall evaluation; z = -4.003, p < .001, n = 120, r = .37) and reported to perceive the discussions with the trainer to be more helpful than at 6-month follow-up (z= -9.006, p< .001, n = 120, r = .82).

Discussion

This study accompanied findings from the primary analyses (Jansen et al., 2021) and qualitative evaluation (Reicherzer et al., 2021). By asking participants for their detailed view on the delivery, content, and their perceived outcomes, this study followed recommendations for the process evaluation of complex interventions (Moore et al., 2015) and added important insights for a potential large-scale implementation of both programs.

Both LiFE and gLiFE participants mostly had similar views on the two interventions, indicating that gLiFE might be an adequate alternative to the original LiFE format. The fact that participants' ratings stayed stable over time to a large extent not only supports the acceptability of both formats, but might also translate into long-term maintenance of the LiFE activities. The few differences which emerged provide starting points for intervention refinement. For example, short one-on-one consultations during the group training might promote the perceived helpfulness of the discussion with the trainer in gLiFE.

In summary, both LiFE and gLiFE participants rated the two interventions formats positively and had similar views on the overall evaluation, perceived outcomes, mode of delivery, and materials and contents, including over time. These findings underpin the findings from the LiFE-is-LiFE trial that the recently developed group-based LiFE program is a promising alternative to the individual format.

4.6. Publication VI: Changes in Psychological Determinants of Behavior Change After Individual vs. Group-Based Lifestyle-integrated Fall Prevention: Results From the LiFE-is-LiFE Trial

Sarah Labudek, Lena Fleig, Carl-Philipp Jansen, Franziska Kramer-Gmeiner, Corinna Nerz, Lindy Clemson, Jochen Klenk, Clemens Becker, & Michael Schwenk (under review).

Background

The LiFE and gLiFE intervention were shown to effectively reduce fall rate and promote physical activity (Jansen et al., 2021). However, the underlying processes which are assumed to drive the underlying behavior change process have not yet been examined, leaving it unclear how LiFE and gLiFE might potentially induce their effects. It remains uncertain how the intervention components (BCTs; Michie et al., 2011) of LiFE and gLiFE affect theory-based psychological determinants of behavior change. Therefore, the aim of this study was to examine the differential effects of LiFE and gLiFE on theory-based, psychological determinants of behavior change, i.e., motivational and volitional determinants, habit strength, and more general psychological determinants such as autonomy, competence, relatedness, and intrinsic motivation. The hypothesis was that both formats induce similar effects on most psychological determinants of behavior change, except relatedness, where gLiFE was assumed to be superior to LiFE.

Methods

This study presented a secondary analysis of the LiFE-is-LiFE trial (Jansen et al., 2018; see chapter 3.2 and 3.3). At up to six measurement points (i.e., baseline [T1], last intervention session [T2], booster phone calls 1 [T3] and 2 [T4], 6-month [T5], and 12-month follow-up [T6]), psychological determinants of behavior change were assessed with Likert-scaled questionnaires. During the development process of gLiFE (Kramer et al., 2020), the BCTs used in LiFE and gLiFE were specified and mapped to the HAPA (Schwarzer, 2008), self-determination theory (R. M. Ryan & Deci, 2000), and theory on habit formation (Gardner & Lally, 2018). Regarding motivational determinants of behavior change, self-efficacy, outcome expectancies, risk perception, and intention were assessed. Volitional determinants of behavior change included action planning, coping planning, and action control. Habit strength was assessed as an indicator of behavioral automaticity starting at the last intervention session. General determinants of behavior change derived from the self-determination theory encompassed autonomy, competence, relatedness, and intrinsic motivation. Twelve LMMs were specified in R (version 4.0.3.) using data from participants who attended at least one intervention session (n = 294). In each model, the respective psychological determinant was specified as the outcome, being predicted by time (effect-coded), intervention format (LiFE/gLiFE; effect-coded)

as well as the interaction between time and intervention format. Based on the LMMs, ANOVAs were specified to examine main and interaction effects.

Results

Regarding motivational determinants of behavior change, both LiFE and gLiFE participants reported a decrease of self-efficacy (LiFE b = -0.23, p = .006; gLiFE b = -0.37, p < .001) and risk perception (LiFE b = -0.28, p < .001; gLiFE b = -0.19, p = .019) at T6 compared to T1. Outcome expectancies were significantly lower in gLiFE (b = -0.29, p = .021) but not in LiFE (b = 0.07, p = .979) participants at T6. Participants' intention to perform LiFE and to engage in an active lifestyle differed greatly over time and between intervention formats. However, there were no pre-post or between-group differences in intention at T6 compared to T1.

LiFE, but not gLiFE participants showed significantly higher levels of action planning (b = 0.80, p < .001) and coping planning (b = 0.63, p = .012) as volitional determinants of behavior change at T6 compared to T1. In contrast, action control increased in both LiFE (b = 0.89, p < .001) and gLiFE (b = 0.64, p = .006).

Regarding habit strength as an indicator for behavioral automaticity, both LiFE and gLiFE participants showed significant decreases from T2 to T3 (LiFE b = -0.48, p = .004; gLiFE b = -0.50, p = .003), but levels of habit strength stabilized over time and stayed stable above mid-scale levels.

Unexpectedly, LiFE participants showed higher values of autonomy at the beginning and at the end of the intervention with no significant pre-post intervention differences. Levels of relatedness decreased significantly over time in gLiFE participants (b = 1.50, p < .001), with LiFE participants again showing higher values than gLiFE participants. There were no pre-post or between-group differences in intrinsic motivation compared to baseline.

Discussion

This study examined for the first time the effects of the LiFE and gLiFE intervention on psychological determinants of behavior change. This is an important step towards understanding how LiFE and gLiFE develop their effects, and, on a larger scale, better understanding the mechanisms behind behavior change interventions. Results show that, overall, LiFE and gLiFE mostly did not promote psychological determinants of behavior change. The only exception were the volitional determinants, indicating that both formats, but especially LiFE, promoted action planning, coping planning, and action control. A possible explanation could be that LiFE participants acquired action planning and coping planning skills more due to close individual trainer supervision. Unexpectedly, LiFE participants showed higher levels of relatedness, which could have resulted from a closer connection to the trainer.

Our findings are in line with a recent meta-analysis, indicating that the effects of physical activity interventions in older adults on psychological determinants of behavior change are overall small, with the strongest intervention effect being found on behavioral regulation (Rhodes et

al., 2021). Future studies could examine how specific BCTs affect theory-based psychological determinants, for example by using factorial designs. As a practical implication, findings suggest that using booster phone calls may help to buffer motivational or volitional dips post intervention.

In summary, this study showed that gLiFE and especially LiFE promote volitional determinants of behavior change. This finding is in line with previous research and adds to understanding the mechanisms beyond LiFE and gLiFE which induce fall risk reduction and physical activity promotion.

5. Discussion

The current work provides evidence for gLiFE to be an effective theory-based fall prevention intervention for older adults aged 70 years and older. Health behavior theory was barely considered in the original LiFE format, even though LiFE aims to initiate a long-term behavior change through habit formation. The presented thesis explicitly considers and tests theory-based psychological aspects of behavior change in the LiFE context in a structured manner. The innovation value of this dissertation project is two-fold. First, gLiFE was developed on the basis of three theories of behavior change: the HAPA, self-determination theory, and habit formation theory, to optimize delivery regarding behavior change. The developed gLiFE concept showed good feasibility and was well accepted by participants. Second, evaluating not only gLiFE's effectiveness in comparison to LiFE, but also its effects on psychological determinants of behavior change and participants' acceptability contributes to a deeper understanding of the underlying psychological processes such as whether and to which extent habits are established.

The results of the evaluation of gLiFE suggest that gLiFE is effective in reducing falls and promoting physical activity as well as volitional determinants of behavior change such as action control. Furthermore, gLiFE is well accepted by participants, which can promote intervention effectiveness. In the following, the findings and implications of the current work will be discussed, also in comparison to LiFE. The following subchapters exceed the discussion parts of the individual publications by comparing LiFE to gLiFE on a superordinate level and providing implications on the basis of the overall results.

5.1. LiFE or gLiFE? Discussion of Similarities and Differences

Even though the research design of the LiFE-is-LiFE trial tested the non-inferiority of gLiFE compared to LiFE, scientific rigor forces a judgement on or tendency towards whether, all findings taken together, one format can be considered better than the other. Based on the findings presented in this dissertation project, similarities and differences between LiFE and gLiFE will be discussed.

5.1.1. Similarities between LiFE and gLiFE

Our findings suggest that both formats were accepted by participants (Reicherzer et al., 2021; Wolf et al., 2022). Participants valued the tailorable and lifestyle-integrated approach (Kramer et al., 2020; Reicherzer et al., 2021) and were positive about the overall evaluation, program outcomes, content, delivery, and materials of LiFE and gLiFE (Wolf et al., 2022). These findings underscore the feasibility of both LiFE and gLiFE. Since participants liked the overarching idea of LiFE, the findings from this dissertation project can also be seen as additional evidence for the feasibility of lifestyle-integrated training (Weber et al., 2018).

LiFE and gLiFE also induced similar effects on motor capacity and perception of functional limitations (Jansen et al., 2021). Regarding effects on psychological determinants of behavior change, both LiFE and gLiFE promoted volitional determinants such as action control rather than motivational or general determinants of behavior change. Levels of habit strength also developed similarly over time, with a significant decrease of habit strength directly after the face-to-face intervention sessions and stable levels until 12-month follow-up.

5.1.2. Advantages of LiFE

LiFE participants acknowledged the training at home and under closer supervision (Reicherzer et al., 2021). Regarding the main outcome of the LiFE-is-LiFE trial, LiFE induced a higher fall rate reduction, -55% compared to -37% in gLiFE. Concerning the effects on psychological determinants of behavior change, LiFE better promoted volitional determinants of behavior change (Labudek et al., 2022), which could have been caused by the closer supervision. Acquiring action and coping planning skills may have worked better for LiFE participants because they potentially received more frequent feedback.

On a superordinate level, LiFE may be accepted by participants due to its lower effort. LiFE participants do not need to travel and can schedule their training sessions flexibly, which was reflected by a very high attendance rate of 8.7 out of 9 sessions in LiFE (Jansen et al., 2021). Conversely, gLiFE participants need to get to the training site and cannot reschedule in case of other appointments. Since all costs were covered by the study and participants all volunteered to participate, this might have not affected the present results. It is, however, imaginable that the participants' effort will be perceived differently when LiFE is carried out under real world conditions.

5.1.3. Advantages of gLiFE

gLiFE participants showed a significantly higher increase in steps per day than LiFE participants (difference of 880 steps, $p = .007$), pointing towards gLiFE's superiority for physical activity promotion. This finding stands in the face of the significantly lower attendance rates in gLiFE (7.8 out of 9 sessions), suggesting that the lower "dosage" of gLiFE was still sufficient to induce these effects. Our research design and analyses reveal no clear explanation for these findings and stand in opposition to a Cochrane review which found no difference in intervention effectiveness caused by delivery format (Sherrington et al., 2020). It is possible that the effect was induced by factors which were not assessed or even part of the intervention. For example, participants were forced to visit the training site, often by public transportation or other means. This could have led to a stronger routine in going outdoors or travelling to the city that persisted over time, irrespective of the intervention having ended. LiFE participants, in contrast, practiced with the trainer at home which might have made the balance and strength activities more salient than the principles for physical activity promotion.

Social support was the most discussed factor regarding a potential advantage of gLiFE over LiFE in the development process. Qualitative (Kramer et al., 2020; Reicherzer et al., 2021) and quantitative (Wolf et al., 2022) results reflect that participants appreciated the presence of peers. However, results on relatedness as an indicator of experienced social connectedness revealed LiFE to induce higher levels of relatedness than gLiFE (Labudek et al., 2022). Potentially, LiFE participants felt a stronger connection to the trainer, while seven sessions for gLiFE participants were not enough to befriend peers. Support for this assumption is given by study results showing that older adults pursue fewer social contacts and the number of new friendships declines with age (Shaw et al., 2007).

Even though the cost-effectiveness analyses are not the focus of this dissertation project, they need to be considered in the face of potential large-scale implementation of gLiFE. We found intervention costs of gLiFE to be lower than in LiFE, which may be attractive for future payers like health insurances. Even the fact that the willingness to pay from a participants' perspective was higher for LiFE than for gLiFE did not compensate for LiFE's higher intervention costs (Gottschalk et al., 2021). Furthermore, compared to LiFE, gLiFE was likely to be cost-effective for increasing physical activity (Gottschalk et al., 2021). Hence, from the payer's perspective, gLiFE is the superior program in terms of an increase in physical activity. As a result, cost bearers of care for age-related health prevention are recommended to implement gLiFE rather than LiFE. Funding gLiFE as part of standard care would ultimately lead to a broad support for healthy aging.

5.1.4. Summary

In summary, LiFE and gLiFE both have their advantages. Based on the findings from the studies included in this dissertation project, no clear superiority of one or the other program could be determined. When evaluating complex interventions, it is important to not only focus on (cost-)effectiveness, but also consider acceptability and theoretical aspects (Skivington et al., 2021). Thus, the "pure" advantage of LiFE in reducing activity-adjusted falls needs to be weighed against gLiFE's lower intervention costs and significant increases in physical activity. Furthermore, although LiFE was superior in inducing long-term effects on action and coping planning, levels of habit strength as a key indicator for behavioral maintenance were similar between formats. This suggests that both formats might be equally capable of promoting habit formation. From a participants' perspective, gLiFE was evaluated similarly compared to LiFE, suggesting that both programs are attractive for the target group.

5.2. Contribution of the Key Findings to the State of Research

The main findings of the six publications are summarized in Table 5. The first paper (Labudek et al., 2021; chapter 4.1), in which the HAPA was extended by intrinsic motivation and applied to older adults' walking duration, highlighted the importance of intrinsic motivation for older

adults' physical activity. So far, the HAPA has been applied to many health behaviors such as physical activity, but has rarely been applied to the target group of older adults or linked to accelerometry-based physical activity. By testing and refining health behavior theory on the basis of a sample of older adults, this study considers specific characteristics of older individuals in physical activity behavior, as requested by researchers (Klusmann et al., 2021; Ziegelmann & Knoll, 2015). The fact that social-cognitive determinants were not related to older adults' walking duration contradicts findings from another study on self-reported physical activity (Bierbauer et al., 2017) and suggests that other factors might be associated with older adults' sensor-measured walking duration. Intrinsic motivation was the only factor which was significantly associated with walking duration, aligning with findings from other studies (Arnautovska et al., 2019; Dacey et al., 2008; Ferrand et al., 2014). However, those studies often use self-reporting (i.e., questionnaires) for physical activity assessment, which can be biased (Harris et al., 2009; D. J. Ryan et al., 2018; Taraldsen et al., 2012). In contrast, this study combined the testing of an extended version of the HAPA with state-of-the-art physical activity assessment (Grant et al., 2006; L. F. R. Lee & Dall, 2019). The findings of this study could only partly be applied to gLiFE, because of the research methodology (i.e., mini-longitudinal design with the baseline data) and focus (i.e., walking duration as an important, but very specific surrogate of physical function) of the study.

In the second publication (Kramer & Labudek et al., 2020; chapter 4.2),the gLiFE concept and its initial feasibility testing was presented. The development of gLiFE followed scientific guidelines (Craig et al., 2008; Moore et al., 2015) and the reporting of the intervention content was ensured using the BCT taxonomy (Michie, Ashford, et al., 2011). This, in turn, ensured the reporting of gLiFE as a behavior change intervention in a detailed and standardized manner, as it is often requested (Hagger, Cameron, et al., 2020). In the future, this will enable better testing, replication, and implementation of gLiFE. The theoretical basis of gLiFE was strengthened, mapping it to the HAPA, self-determination theory, and habit formation theory. Involving users in the early stage of intervention development enabled us to revise the gLiFE concept in response to older adults' needs and preferences (Moore et al., 2015). The successful feasibility testing paved the way for gLiFE to be compared to LiFE in the large non-inferiority trial. Initial findings on the psychological determinants of behavior change indicated that gLiFE participants reported increased levels of psychological determinants of behavior change.

Findings of the third paper (Reicherzer et al., 2021; chapter 4.3), which contained the qualitative evaluation of LiFE and gLiFE from a participants' perspective, suggest that both formats were equally accepted by participants. LiFE participants particularly appreciated the one-to-one supervision, whereas gLiFE participants valued the group interaction. The social interaction with both trainers and peers and the functional nature of the LiFE activities, which is closely related to the value of physical activity, could have led to the high acceptability of LiFE and

gLiFE (Devereux-Fitzgerald et al., 2016). Regarding behavior change, LiFE and gLiFE participants reported that habits had formed. Since acceptability is necessary for intervention effectiveness (Sekhon et al., 2017), this study adds important insights into possibilities for refining LiFE and gLiFE. For example, paperwork could be simplified and gLiFE participants could be better supported in finding appropriate practice situations for the LiFE activities.

The non-inferiority testing of gLiFE, which was reported in the fourth paper (Jansen et al., 2021; chapter 4.4), contributed to the current state of research in several ways. First, by its innovative design, the non-inferiority trial facilitates the goal-oriented intervention refinement towards better large-scale implementability. The assessment methods used in the trial, i.e., prospective falls assessment (Hauer et al., 2006) and sensor-based physical activity assessment, follow recommendations for high-quality research (Grant et al., 2006; L. F. R. Lee & Dall, 2019) and are an enhancement of the original LiFE trial (Clemson et al., 2012). Second, analyzing the intervention costs as a second primary outcome contributes to large-scale implementability (Skivington et al., 2021). gLiFE's non-inferiority compared to LiFE showed to be inconclusive regarding activity-adjusted falls rate. Nevertheless, gLiFE effectively reduced falls to a large degree (-37%), even when compared to average effectiveness rates of fall prevention interventions (Sherrington et al., 2019). Thus, gLiFE can be regarded as a promising format, especially when considering the significantly higher increase of physical activity and the lower intervention costs.

The results of the fifth paper (Wolf et al., submitted; chapter 4.5) complement the qualitative study by involving users again, now with the aim of quantifying the satisfaction and perceived effectiveness of LiFE and gLiFE alongside the evaluation of program-specific characteristics such as the use of methods like action planning. Involving two assessment points, post intervention (6-month follow-up) and over half a year after intervention cessation (12-month follow up), this study contributed insights on how the participants' perceptions differ between formats and change over time. Mostly, LiFE and gLiFE participants shared views on both formats and reported overall satisfaction with the programs and their perceived effectiveness. The evaluations also largely stayed stable over time, supporting the acceptability of LiFE and gLiFE, including regarding long-term effects.

In the sixth and final paper (Labudek et al., under review; chapter 4.6), gLiFE was evaluated with regard to effects on psychological determinants of behavior change. Including psychological endpoints into intervention evaluations and explicitly testing the assumed theoretical principles can maximize the usefulness of health behavior theory (Carey et al., 2019). This study showed that both LiFE and gLiFE mainly promote volitional determinants of behavior change, and merely induce long-term changes to motivational or general determinants of behavior change. Regarding habit strength, which can be considered the most important indicator for long-term maintenance of LiFE, LiFE and gLiFE participants seemed to develop and maintain

habit strength similarly, with above average levels of habit strength at long-term follow-up. Our findings mirror the ones from a recent meta-analysis which examined the effects of potential mediators for changes in physical activity (Rhodes et al., 2021). The results show that currently discussed theory-based psychological determinants only showed small effects on physical activity in adults. Nevertheless, this study examined the effects of LiFE and gLiFE on potential psychological determinants of behavior change and thereby sets the starting point for future research.

5.3. Implications for Research

The methodology and outcomes of this dissertation project provide starting points for future theoretical and empirical work. A summary of the theoretical and practical implications by publication is provided in Table 5. In this section, the overarching implications of all publications will be discussed.

5.3.1. Advancing research methodology in the LiFE context

A closer investigation of the effectiveness of applied BCTs and LiFE activities could further improve gLiFE's effectiveness. Experimental or factorial designs (Collins et al., 2009) in which (sets of) specific BCTs tackling motivation, volition, or habit formation are tested may help to understand which BCTs make gLiFE effective. Findings on the dose-response relationship in LiFE and gLiFE suggest that participants like some LiFE activities more than others (Nerz et al., 2022), which is also reflected in the qualitative evaluation (Reicherzer et al., 2021). To evaluate the effectiveness and dose-response relationship of the LiFE activities in more detail, a reliable and valid measure of adherence is needed. The assessment of adherence to the LiFE activities was based on the (German) *Exercise Adherence Rating Scale* (EARS; Newman-Beinart et al., 2017), which is not yet validated. More importantly, is not tailored to the LiFE context. Future studies could use *ecological momentary assessment* (EMA) to examine behavioral frequency of the LiFE activities and prevent recall bias (Dunton, 2017). Furthermore, EMA studies would facilitate the context-dependent assessment of the LiFE activities, which is important to better understand habit formation in the LiFE context (Gardner et al., 2021). Aside from self-reporting, increases in sensor-based up-time (i.e., including standing and walking) could be an indirect indicator for the performance of the LiFE activities, since almost all are performed while standing.

Table 5

Key Findings and Implications for Practice and Research

Chapter	Paper	Key findings	Implication for research	Implication for practice
4.1.	Labudek et al. (2021)	Intrinsic motivation, but not HAPA-related predictors of health behavior are related to objectively measured physical activity. → Older adults who find a sense of enjoyment while walking, tend to walk more	Motivation quality in terms of intrinsic motivation can help to gain a deeper understanding of older adults' walking duration HAPA-variables may not be appropriate for explaining older adults' walking duration because of their cognition-based nature Future studies should aim for a closer fit between self-report measures and sensor-based measured walking duration	Fall prevention programs may try to foster intrinsic motivation, e.g., by focusing on autonomy-supportive delivery
4.2.	Kramer et al. (2020)	Development of the gLiFE program was successful; small pilot revealed that participants accepted the program as shown by high levels of satisfaction → gLiFE as a new fall prevention program can now be tested in a larger trial in comparison to LiFE	The theoretical basis for gLiFE has been developed from a behavior change perspective and the effects on psychological outcomes need to be tested in a larger sample	gLiFE with its theory- and evidence-based approach and its low resource-intensity could be attractive for policy makers and health insurances The gLiFE manual ensures high fidelity during a large-scale roll-out of gLiFE
4.3.	Reicherzer et al. (2021)	gLiFE and LiFE seem to be acceptable, both learning settings (i.e., in a group or at home) seemed to induce (self-reported) habit formation → gLiFE seems to be equally well-accepted as LiFE	Assessment of acceptability as an important part of program evaluation; user involvement can shape further refinement of gLiFE	Trainers who teach gLiFE should focus on reaffirming participants in their own decision-making and respecting individual capabilities as important factors for building motivation and confidence in gLiFE

4.4.	Jansen et al. (2021)	Non-inferiority of gLiFE could not be confirmed, but both formats showed better fall rate reduction than in the reference trial (gLiFE 37%, LiFE 55%) gLiFE leads to a significantly higher increase in steps/day than LiFE → Despite a smaller fall rate reduction in gLiFE than in LiFE, gLiFE is valuable due to its effectiveness in promoting physical activity	By refining existing interventions such as LiFE, their feasibility and cost-effectiveness can be improved It is not clear why gLiFE induced the strong increase of physical activity	gLiFE is a valuable alternative to LiFE, especially from the payers' perspective with regard to physical activity improvement Both programs could be offered to older adults, depending on their needs and preferences
4.5.	Wolf et al. (submitted)	Few between-group differences suggest that gLiFE and LiFE participants mainly shared positive views regarding the program overall, program-specific aspects such as delivery and materials, and perceived outcomes Evaluations remained stable over time, and pre-post significant differences → gLiFE shows similarly high acceptability as LiFE	Future studies could examine how (cost-)effective additional booster phone calls or adaptations like one-on-one consultations in gLiFE might be	For participants, both LiFE formats seem valuable Trainers should focus on the principle of upgrading so that participants challenge themselves sufficiently while training alone
4.6.	Labudek et al. (under review)	LiFE and gLiFE mainly induce changes in volitional determinants of behavior change; habit strength reached medium levels and stayed stable over time → gLiFE seems to work similar to LiFE regarding psychological determinants of behavior change	Assessing effects on psychological determinants should be incorporated more often in the evaluation of theory-based behavior change interventions Applying a multi-theory approach was helpful for understanding the processes underlying LiFE and gLiFE, although only long-term effects on volitional determinants of behavior change could be identified	Booster phone calls could help to lift levels of intention and volitional determinants. However, their practicability and cost-effectiveness for gLiFE needs to be reviewed in implementation settings Habit strength could be used as an indicator for the necessity of (continuous) trainer support

One of the most important methods to assess LiFE's and gLiFE's effectiveness could be applying *N-of-1 studies* (Kwasnicka et al., 2018). N-of-1 studies aim to find the optimal intervention for an individual patient by following that one individual or a small set of patients closely and investigating efficacy or potential side-effects using objective data-driven criteria (Lillie et al., 2011). Examining within-person variability of the behavior change process through LiFE could account for the large heterogeneity between older adults and stands in opposition to the reasoning behind behavior change models, which mostly assume the behavior change process works similarly in every individual.

Evidence against this assumption in the context of older adults' physical activity is provided by Bierbauer et al. (2017), for example. Findings of their study suggested psychological determinants of older adults' physical activity are less in line with the HAPA when considering the intraindividual than when considering the interindividual level. In the LiFE-context, N-of-1 studies could bring additional insights into the effectiveness of LiFE for certain (groups of) older adults or the effectiveness of single LiFE activities.

Aside from finding out what works on the individual level, potential harms of LiFE and gLiFE could also be assessed in more detail. The *dark side* of behavioral interventions has often been neglected (Bonell et al., 2015). In the LiFE-is-LiFE trial, adverse events such as falls which were potentially associated with the intervention were assessed, but there might also be psychological harms which were not considered. For example, it is imaginable that the LiFE approach (i.e., to make daily life more challenging) induces stress or older adults get attached to the trainer or the group of peers so that the end of the intervention causes negative affections. Results from one of the included studies suggested that participants reported significantly lower levels of self-efficacy at 12-month follow-up compared to baseline (Labudek et al., 2022), which could have a negative impact on the long-term maintenance of the LiFE activities.

5.3.2. Applying health behavior theory to the LiFE context

Three behavior change theories, the HAPA (Schwarzer, 2008; chapter 1.3.2), the self-determination theory (R. M. Ryan & Deci, 2000; chapter 1.3.3), and theory on habit formation (Gardner & Lally, 2018; chapter 1.3.4) are used in this study. The findings reveal that the HAPA alone might not be useful for explaining older adults' walking duration as a specific surrogate of physical activity (Labudek et al., 2021), but LiFE and gLiFE participants showed increased levels of volitional strategies at long-term follow-up (Labudek et al., 2022). By using the self-determination theory and thereby acknowledging that LiFE is an autonomy-supportive intervention, LiFE seems to be more fulfilling regarding psychological needs as gLiFE (Labudek et al., 2022). The evolvement of habit strength over time was first reported in the LiFE context in this dissertation project, adding evidence for LiFE habits to form and sustain over time to a

certain degree. Taken together, the use of all three theories prove to be relevant for the target behavior of physical activity in older adults.

To take this research further, the integration of those theories could be tested. An example would be the integrated behavior change model, which combines autonomous motivation with the theory of planned behavior and action planning in the physical activity context (Hagger & Chatzisarantis, 2014). Arnautovska et al. (2017) applied the integrated behavior change model to a sample of older adults (M_{age}= 73.8 years) and additionally extended it by habit strength. The model showed a good fit to the data, indicating both conscious and automatic processes. However, the study did not comprise an intervention, only had a short follow-up period (2 weeks), and physical activity assessment was based on self-reporting. Future studies could combine the HAPA, self-determination theory, and habit formation using sensor-based physical activity as an outcome behavior and including a long-term follow-up.

Psychological determinants of behavior change have been shown to mostly induce small effects on behavior (Rhodes et al., 2021; Zhang et al., 2019). Therefore, broader theoretical models might be more appropriate to predict and promote physical activity as a multifactorial construct in older adults. For example, Webber et al. (2010) proposed a model for older adults' mobility which also includes environmental and cultural factors. The built environment is crucial in the LiFE context because environmental cues ought to trigger the LiFE activities. Aside from the built environment, the social environment could also be considered more strongly in the LiFE context. Other studies have found evidence for the importance of the social environment to older adults' physical activity behavior (Fleig, Ashe, et al., 2016; Schüz et al., 2012; Sniehotta et al., 2013). For example, LiFE activities could be planned within dyads (Carr et al., 2019), or informal caregivers such as family members could be included in delivering and practicing LiFE.

5.3.3. Reconsidering habit formation in the LiFE context

Habit formation as the psychological indicator of behavioral maintenance in the LiFE context needs to be investigated in more detail. Based on the current work, multiple questions arise on the concept of habits in the LiFE context and how to best promote the formation of LiFE habits. First is the question of whether habit formation is even the end goal of LiFE, considering that participants need to mindfully perform the LiFE activities and adjust the intensity level as training progresses. The distinction between habitual instigation and execution (Gardner et al., 2016) could be useful to examine the nature of habits in the LiFE context in more detail. Differentiating between the habitual initiation (or instigation) vs. performance (or execution) of exercise has been shown to be predictive of adult's exercise frequency (Phillips & Gardner, 2016). The fact that habitual instigation but not execution was a predictor for physical activity

behavior suggests that interventions might be more effective when they tackle the habitualization of physical activity instigation. The goal of LiFE and gLiFE would consequentially be to habitualize the initiation of the LiFE activity and make the performance as mindful as possible so that participants could challenge their physical boundaries and thereby improve their physical function (see chapter 5.4.1).

Second, studies have shown that habit formation of *one* self-chosen health habit takes about 2.5 months, with large variability between individuals (Keller et al., 2021; Lally et al., 2010). The LiFE approach, however, requires older adults to form *up to 14* new habits. Theoretically, simultaneously forming multiple habits is possible and has been examined empirically, especially in the nutrition context (Cleo et al., 2019; McGowan et al., 2013). Habit formation could be hampered when participants mix up contexts and LiFE activities so that no clear cue-behavior association arises. However, according to the so-called strategy of piggy-backing (Gardner et al., 2021), one LiFE activity could serve as the contextual cue to perform another, resulting in a (longer or shorter) training routine. It is arguable whether the LiFE program should be restricted to fewer activities. Although the LiFE activities were gradually introduced over the course of the intervention, the time lag between the implementation of new LiFE activities might have been too short to establish high enough levels of habit strength for each LiFE activity, which could explain that overall habit strength did not reach peak levels (Labudek et al., 2021). From a sport scientific perspective, though, the highest amount of LiFE habits possible might ensure a sufficient training stimulus (i.e., frequency, duration) to improve or maintain physical function (see chapter 1.2).

Applying even more measurement points by using intensive longitudinal data, i.e., using high-frequency and high-density data, might help to better understand the habit formation process in the LiFE context. Two questions might be of particular importance for the LiFE context. First, finding out when older adults reach peak habit strength, which has been shown to vary greatly between individuals (Keller et al., 2021; Lally et al., 2010), could advance health behavior research in older adults (Ziegelmann & Knoll, 2015). Differences in time to peak habit strength might also impact considerations on intervention length and trainer support. If some older adults take longer to form stable LiFE habits, they might profit from prolonged supervision. Thus, habit strength could be used as an additional indicator for the necessity of trainer support. Second, examining when participants are switching between conscious processes such as action control and implicit processes like habit strength (Dunton et al., 2021) could help to identify situations in which older adults are particularly vulnerable for lapses (Roordink et al., 2021). Bringing focus to such situations and developing skillful coping mechanisms together with participants could ensure long-term maintenance of the LiFE activities.

Lastly, it should be critically reviewed whether habit formation is the right intervention strategy for older adults altogether. Although the LiFE approach seems to circumvent many of the barriers older adults report against engaging in physical activity (see chapter 1.2.5 and 1.2.8), the current findings suggest that some older adults did not like the rigid structure required for habit formation (Kramer et al., 2020; Reicherzer et al., 2021). Indeed, studies have shown that strong pre-existing habits for a certain behavior will render implementation intentions for new behaviors ineffective (Adriaanse, van Oosten, et al., 2011; Webb et al., 2009; see also Hagger & Luszczynska, 2014). Given the fact that older adults may have executed their daily routines for decades, it could be better to focus on implementing one training routine a day instead of changing multiple daily routines which are strongly ingrained. A potential compromise would be to focus on forming *higher-order habits* (Phillips et al., 2019), for example, by performing the LiFE activities flexibly in all waiting situations instead of finding one daily routine which cues each LiFE activity.

5.3.4. Investigating gLiFE's implementability

Since the findings of this project point towards the potential for gLiFE to be implementable on a larger scale, testing implementation in a scientific scope would be a logical next step. An implementation trial which involves stakeholders like physiotherapists, general practitioners, or local public health leaders could reveal which challenges gLiFE would face when being implemented (Gearing et al., 2011; Lach et al., 2011). Important aspects would be to assess fidelity, dose, and adaptation reach (Moore et al., 2015). The detailed gLiFE manual ensured fidelity for the LiFE-is-LiFE trial (Kramer et al., 2020), although fidelity was not explicitly assessed or evaluated. Future studies could show if the gLiFE manual also ensures fidelity on a larger scale.

Another important step would be to assess the effectiveness of gLiFE in different implementation contexts. It is imaginable that gLiFE would be more effective in more rural areas in which community support, especially among older adults, might be stronger (van de Vijver et al., 2018). Participants could interact more closely, buffering each other's motivational slumps or inciting each other to practice more (intensely). Most urgently, gLiFE would need to be implemented in areas with a higher concentration of individuals with low socio-economic status (SES). A growing number of research points towards differential effects depending on SES (Schüz, 2017). Since lower SES is also associated with a lower health status (Rahman et al., 2016) and a higher number of functional limitations in older age (Bloomberg et al., 2021), reaching participants with a lower SES is highly desirable for future research.

Furthermore, as diversity increases in older age and many older people experience health constraints, gLiFE should be also tested in subpopulations, as it was done with LiFE. For example, LiFE has been applied to populations with vision impairment (Keay et al., 2017), and

see Hezel et al. (2021) for an overview of the adaptations of LiFE. The approach of Li et al. (2018) to implement LiFE at retirement homes could be a context in which gLiFE might be implemented successfully.

5.4. Implications for Practice

Not only implications for research, but also practical implications can be drawn on the basis of the present findings. In the following, these implications will be divided into implications for trainers and potential payers.

5.4.1. Implications for trainers

Our results show that participants appreciated the trainers' personalities (Reicherzer et al., 2021; Wolf et al., 2022). Therefore, future trainers should be chosen not only based on their professional skills, but also regarding their personalities. Based on the self-determination theory and findings from empirical studies (Hawley-Hague et al., 2016), trainers should provide choices and act in an autonomy-supportive manner. Since the theoretical background and theoretical inputs on health behavior change might be new to other professions such as physiotherapists, trainers should receive training before delivering gLiFE.

To increase engagement, trainers should focus on making gLiFE enjoyable (Labudek et al., 2021). The gLiFE manual explicitly introduces an autonomy-supportive teaching style, which might explain participants' significantly higher levels of intrinsic motivation at 6-month follow-up (Labudek et al., 2022). In line with this finding, a self-managed fall prevention intervention has shown to effectively support basic psychological needs (Pettersson et al., 2021). To even better prepare participants to manage their training individually long-term, trainers could additionally provide participants with techniques to self-manage their motivation in the future (Knittle et al., 2020).

Another recommendation for trainers based on the present findings (Reicherzer et al., 2021; Wolf et al., 2022) and scientific evidence (McEwan et al., 2020; Noar et al., 2007) would be to ensure the best tailoring for each individual. This not only implies finding feasible daily situations to perform the LiFE activities, but also adapting the intensity of the LiFE activities to the individual training progress. To do so, it might be necessary to question participants' attitudes towards aging and physical activity (see chapter 5.6.1). However, this could be a challenging endeavor, since industry as well as family members often seem to fuel the belief that older adults should "take it easy" or not strain themselves too much. Of course, participants should not be overstrained, but they should understand that putting some strain on the body can help to prevent the downward spiral of losing physical function and decreased activity levels (chapter 1.1.3).

5.4.2. Implications for stakeholders

When promoting gLiFE to potential stakeholders such as health insurances or municipal sports clubs, the benefits of gLiFE should be stressed. gLiFE stands out with its, its cost-effectiveness in enhancing physical activity and its acceptability. The acceptability by the target group can be used as a strong argument in advertisement campaigns.

The LiFE-is-LiFE participants were already highly motivated at baseline (Labudek et al., 2021), suggesting that it might be hard to recruit participants who are not motivated to engage in fall prevention. Involving general practitioners in the promotion of gLiFE could be a possibility to reach individuals with low motivation to change (Elley et al., 2003; Hinrichs & Brach, 2012). A potential pathway to enhance older adults' motivation for and engagement in physical activity or fall prevention interventions might be to promote social interaction (Devereux-Fitzgerald et al., 2016). For gLiFE, this might be also important because the present findings indicate lower levels of relatedness post intervention (Labudek et al., 2022), even though gLiFE-participants highlighted the presence of peers in the focus group interviews (Reicherzer et al., 2021). Arnautovska (2017) proposed framing physical activity interventions for older adults more broadly and in a more emotionally meaningful way. For example, older adults could be involved in volunteering projects, as done by (Fried, 2004). In their study, the involvement of older adults in elementary schools positively affected older adults' strength and walking speed. Thus, for potential payers, it might be worthwhile to embed or connect the LiFE approach to social engagement.

Lastly, since gLiFE's non-inferiority regarding activity-adjusted falls could not be confirmed, the LiFE program may be attractive, with its large effects on fall rate reduction (-55%), so that potential payers might also evaluate under which conditions LiFE could be implemented on a larger scale. An ideal scenario would be that participants could choose which format they would like to attend depending on their personal preferences.

5.5. Strengths and Limitations

Several strengths of this dissertation project need to be highlighted. By using a theory-based and mixed-methods approach, this project meets current scientific standards for intervention development (Craig et al., 2008) and evaluation (Datta & Petticrew, 2013; Moore et al., 2015). Using qualitative and quantitative methods side-by-side allowed clarification and facilitated interpretation of results (Matthews & Simpson, 2020). The design of the superordinate LiFE-is-LiFE study, including the test of gLiFE's non-inferiority with sensor-based physical activity assessment and prospective fall detection, allowed the collection of high-quality data. User involvement and cost analyses broadened the scope of the evaluation (Craig et al., 2008; Moore et al., 2015), ensuring that gLiFE is accepted by participants (Sekhon et al., 2017). Another strength of the trial was the long-term follow-up of 12 months with the aim of evaluating long-

term effects beyond the critical point of 6 months, where many interventions lose effectiveness (McEwan et al., 2020; Sansano-Nadal et al., 2019). Having conducted this research within an interdisciplinary team met the complexity of long-term behavior change in the highly relevant and growing target group of fall-prone, community-dwelling older adults.

The inclusion of the health behavior change perspective enriched the LiFE-is-LiFE trial in both the development and evaluation process. By bringing in a stronger focus on the behavior change theory, the theoretical foundation of gLiFE was strengthened, and it extended the evaluation to the effects on psychological determinants of behavior change. With its refined program theory, this dissertation project meets new recommendations for the evaluation of complex interventions (Skivington et al., 2021). Using the BCT taxonomy to report the active ingredients of LiFE and gLiFE strengthens the intervention concept, facilitates future research, and could guide large-scale implementation (Michie & Johnston, 2013). With the help of the gLiFE manual, trainers with little or no prior knowledge on behavior change can acquire the content easily and deliver gLiFE with high fidelity, which is important for large-scale implementation. Lastly, the evaluation of gLiFE's effects on psychological determinants of behavior change is a first step towards understanding how gLiFE elicits its effectiveness.

On the other hand, the current work needs to be considered in light of several limitations. The publications have the general limitations of quantitative questionnaires and qualitative data, such as social desirability (N. Bergen & Labonté, 2020) or response bias (Paulhus, 1991), and there are also study-specific limitations such as the deviation of the study protocol due to the Covid-19 pandemic and the lack of fidelity assessment, which have been discussed. There are three other main limitations which are discussed in more detail below.

First, although the non-inferiority design yields benefits in terms of efficiency for research and attractiveness for participants, the lack of a control group limits the present findings. Differences from the reference trial in terms of organizational changes and the fact that the study sample showed higher physical activity and lower falls incidence at baseline impair comparability between the results from the current trial and the original trial by Clemson et al. (2012). Furthermore, the psychological mechanisms cannot be compared with the reference trials, since they were first examined in this project.

Second, limitations on the assessment and measurement need to be considered. Although choosing steps per day as a surrogate for physical activity might be appropriate for the target group of fall-prone older adults, increasing walking behavior is only one part of LiFE. Adequately assessing the behavioral performance of the LiFE activities is challenging, especially when considering the amount of LiFE activities and their habit-based nature. The limitations of the EARS as a retrospective self-report used as an indicator for adherence to LiFE are discussed in chapter 5.3.1. The findings on psychological determinants of behavior change might be limited due to their degree of dissolution and due to a low level of correspondence between

psychosocial determinants (e.g., referring to physical activity in general) and sensor-based data (e.g., using walking duration as a specific surrogate). Additionally, habit strength was assessed on average across all LiFE activities. Those ratings might be highly biased by outliers, like LiFE activities participants do not like or perform. However, assessing the habit strength separately for each of the 14 LiFE activities would have led to an enormous participant burden. Future studies could examine habit strength of specific LiFE activities or assess user profiles. To create a better match between psychosocial questionnaire data and sensor-based measurements, future studies could test whether tailoring improves the predictive value of items (e.g., “I intend to walk longer durations at a faster pace”; see also Klusmann et al., 2021). A last point regarding assessment is that the fulfillment of psychological needs was not assessed at 6-month or 12-month follow up, again to reduce participant burden. The findings of a meta-analysis that interventions based on the self-determination theory seem to develop their effectiveness in the long run (Ntoumanis et al., 2021), so the present findings could have also yielded long-term increases in autonomy, competence, and relatedness, but this was not captured by the assessment battery of the trial.

Third, the findings of this dissertation project show a restricted generalizability to the general population of older adults. The study population contained mostly female, highly-motivated older adults without cognitive impairment. The lack of males participating in health behavior interventions and physical activity interventions has been noted in other studies (Cooke & Jones, 2017). Based on the fact that men are generally more active than women, also in older age (Finger et al., 2017), a potential explanation might be that older men who are willing and capable of engaging in physical activity already do so without seeking interventional support. However, since older women experience more functional limitations (Bloomberg et al., 2021) and have a higher risk of falling (Deandrea et al., 2010), the overrepresentation of women might have been beneficial in the context of the LiFE-is-LiFE trial. Motivation has been shown to be an important barrier for older adults’ physical activity behavior (Baert et al., 2011; Gellert et al., 2012; Hagger et al., 2002), so the involvement of individuals who are not or are barely motivated to take up a more active lifestyle might have yielded into different results. Although recruiting a representative sample of community-dwelling older adults at risk of falling was not the goal of the study, it is possible that these findings are biased on the basis of the participants’ characteristics of the drawn sample.

5.6. Suggestions for the Refinement of LiFE and gLiFE

This section gives suggestions for the refinement of LiFE and gLiFE. With regard to the development of complex interventions, the current findings could provide a starting point for another iteration in the development process (Craig et al., 2008; Skivington et al., 2021). In more detail, refinement could be used to tailor LiFE and gLiFE even better to participants’ needs (Wiltsey

Stirman et al., 2019) or to further increase (cost-) effectiveness. The following suggestions are uniquely displayed here, combining all results from the current work.

5.6.1. Refining contents

Aside from reconsidering the optimal number and introduction of LiFE activities as well as circumstances for habit formation (chapter 5.3.3) and the potential integration of LiFE into more sociable contexts (chapter 5.4.2), tackling attitudes towards aging might increase gLiFE's effectiveness.

When it comes to physical activity, negative attitudes towards aging could imply that older adults think about themselves as "not sporty", or that physical activity might cause injuries (Chalabaev et al., 2013). Negative attitudes towards one's own aging have been found to negatively impact self-regulatory strategies for health behavior (Wurm et al., 2013). Another study found that stronger beliefs about the risks of physical activity predicted lower physical activity levels in older adults (Emile et al., 2014). On the other hand, studies suggest that positive attitudes towards one's own aging are positively associated with physical activity engagement (Emile et al., 2014; Levy & Myers, 2004).One study found that negative views on aging are modifiable, but this did not improve the effects of an exercise intervention on self-rated physical performance (Beyer et al., 2019). More recent research explicitly targets negative views on aging in health interventions and examines the effectiveness on both self-reported and accelerometry-based physical activity (Brothers & Diehl, 2017; Diehl et al., 2020).

The basic assumption of the LiFE approach, which is to make the everyday life more challenging and to put some stress on older adults (Clemson et al., 2012), might clash with older adults' negative attitudes towards aging and physical activity. In order to achieve functional improvements, however, participants need to push themselves towards their capability levels and upgrade the LiFE activities according to their own training progress. This might be new to participants and could potentially cause feelings of discomfort. Our findings show that the LiFE-is-LiFE participants reported moderate levels of perceived intensity (Wolf et al., 2022), potentially reflecting studies that suggest older adults to prefer low-intensity physical activity (Bunn et al., 2008). Participants might not have pushed themselves hard enough towards their limits, which also may have resulted in the small to non-existing changes in motor capacity (Jansen et al., 2021). Future trials of the LiFE approach might include a separate theoretical input on attitudes towards aging, where participants' beliefs are openly discussed. It is imaginable that older adults who understand that higher intensity levels promote their health will shape their training differently in the long run and train closer to their capability levels. Besides addressing attitudes towards aging in the intervention itself, considering their potential negative influence on motivation might also be important when addressing unmotivated individuals and advertising LiFE (van Stralen et al., 2009).

5.6.2. Refining the mode of delivery

Originally, the LiFE-is-LiFE trial was set up to modify LiFE's mode of delivery. Since there are further options beyond a group format, it might be worthwhile to consider in which manner LiFE and gLiFE could also be delivered. Findings from the current work suggest that gLiFE participants might have profited from one-on-one consultations (Wolf et al., 2022), such as when finding the appropriate daily situations to practice the LiFE activities (Reicherzer et al., 2021). This could be implemented by either finding slots for individual consultation during gLiFE sessions or by including an individual home visit in gLiFE. In the development process, it was often discussed whether or not to include one home visit, like it was done in another group-based LiFE format (Gibbs et al., 2015, 2019). For gLiFE, a home visit was excluded to ensure large-scale implementability, since a home visit in gLiFE might not be feasible from a payer's perspective. LiFE participants reported an increased perceived importance of the trainer discussion in the long term (Wolf et al., 2022), suggesting that they might have also profited from further trainer support. A possible solution to meet participants' request for more group interaction and conversations (Reicherzer et al., 2021) might be to incorporate additional sessions so that the content can be dispensed. Finding the right dose-response relationship to establish optimal intervention effects and meeting potentially conflicting requirements from different perspectives will be a challenging endeavor for future research.

Transferring (some parts of the) delivery into digital formats could simplify the extensive paperwork which was criticized by participants (Kramer et al., 2020; Reicherzer et al., 2021). Furthermore, digital formats might decrease intervention costs because face-to-face meetings with a trainer could be reduced or fully eliminated. Above all, the importance of the possibility to promote physical activity in older adults without personal contact cannot be underrated in the face of the ongoing Covid-19 pandemic, which had a significant negative impact on older adults' physical activity levels (Schmidt & Pawlowski, 2021). Evidence from systematic reviews largely supports the effectiveness of digital solutions for physical activity promotion in older adults (Kwan et al., 2020; McGarrigle & Todd, 2020).

The extent to which LiFE could be delivered digitally ranges from only providing the activity planner digitally (i.e., on a tablet), to transferring LiFE and gLiFE sessions into the digital space, to solely delivering LiFE via an app, making home visits dispensable. When transferring LiFE to a digital format, recent technological advances such as scanning the whole living environment via smartphones and creating a three-dimensional sketch of participants' homes could support trainings in finding safe and suitable practice situations without the necessity of a personal meeting. A 3D map of a room could also benefit habit formation because the identification of potential cues in the home environment could be simplified. For example, potential training situations could be determined in consultation with the LiFE trainer via an online chat in which both trainer and participant can see the 3D map.

Previously, LiFE has been adapted to young seniors (60-70 years) and tested against a control group in the form of a mobile application and face-to-face delivery (Taraldsen et al., 2019). The results from the trial suggested that the app was feasible, but no significant differences compared to the control group in functional and perceived outcomes were found (Taraldsen et al., 2020). With regard to community-dwelling older adults, recent results from the Standing Tall trial (Delbaere et al., 2015) suggested that a home-based fall prevention intervention which was delivered via two home visits and a tablet was effective in reducing falls over a two-year period (Delbaere et al., 2021). However, the advantages of digital formats should always be weighed against potential harms and challenges of a digital approach (Carter et al., 2018; Murray et al., 2016). For example, older adults' concerns about digital health solutions, such as data security (Klaver et al., 2021), should be considered.

Trainer support could also be adapted, for example by involving trainers who are the same age as participants. Other ideas would be to form tandems with peers who already completed the (g)LiFE program or to involve former (g)LiFE participants as guests in one or more intervention sessions. Findings of the focus group interviews suggested that some participants did not feel understood by trainers of a young age (Reicherzer et al., 2021). Ginis et al. (2013) found that peer-delivered physical activity interventions for and by older adults are similarly effective to interventions delivered by professionals and more effective than control interventions. Further, their findings suggested that peer trainers might foster self-efficacy and self-determined motivation. A study on a public benefit organization found high attendance rates of 77.5% after 6 years and improvements in health status, e.g., indicated by the 6-minute walking test (van de Vijver et al., 2018). Due to these positive effects, it might be worthwhile to test the involvement of peers or peer trainers in the LiFE context.

5.7. Disseminating gLiFE

Since the dissemination of gLiFE was also part of the LiFE-is-LiFE project, several advances have already been made to translate the results of the trial into practice. For example, the study team has designed an informative website (www.life-alltagsuebungen.de) and has conceptualized and provided a trainer workshop to educate potential future LiFE trainers. The focus of the current work on health behavior change through LiFE was part of all dissemination advances, feeding into translation of the research results from the whole LiFE-is-LiFE project. In 2021, gLiFE was successfully carried out in a sports club near Heidelberg. Aside from those practical advances, the publication of the gLiFE manual is currently in preparation. Lastly, the certification of gLiFE as a refundable health program by the central verification center for prevention (ZPP) in Germany is currently in progress.

5.8. Conclusion

The findings presented in this dissertation project provide evidence for gLiFE to be a promising alternative to LiFE and a valuable theory-based fall prevention intervention for older adults with the potential to be implemented on a larger scale. The thus-far neglected psychological mechanisms of behavior change were considered, grounded on well-established theories of health behavior change such as the HAPA, self-determination theory, and habit formation theory.

The new gLiFE format was successfully developed and evaluated along MRC guidelines with a focus on health behavior change. The developed gLiFE concept showed good feasibility and was well accepted by participants. The results of the evaluation of gLiFE suggest that gLiFE is effective in reducing falls and promoting physical activity as well as volitional determinants of behavior change. Although gLiFE's non-inferiority in comparison to LiFE regarding activity-adjusted falls was inconclusive, gLiFE has many advantages such as low costs and good acceptability.

This dissertation project provides several starting points for future research and intervention refinement, for both further promoting long-term behavior change and increasing gLiFE's potential for large-scale implementability. The findings on psychological determinants of behavior change reveal that habit strength of the LiFE activities persists long-term, but more research is needed to fully understand the mechanisms of behavior change in both LiFE and gLiFE. Future studies could apply N-of-1 or EMA designs to examine the habit formation process as a key driver of long-term behavior change in LiFE in more detail. Another possibility to foster the promotion and maintenance of older adults' physical function might be to promote the original idea of LiFE, i.e., finding opportunities in everyday life to challenge physical fitness, even more strongly. This could promote older adults' understanding of training and thereby promote their self-directed training. Regarding mode of delivery, multiple other variations such as peer-led or (partly) digital LiFE formats are conceivable. The dissemination of gLiFE has already been initiated, paving the way for a larger number of older adults being supported in the task of healthy aging.

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List of Tables and Figures

Tables

Figures

List of Abbreviations

AIC	*Akaike's Information Criterion*
ANOVA	*Analysis of variance*
BCT	*Behavior change technique*
BIC	*Bayesian Information Criterion*
CFI	*Comparative Fit Index*
CI	*Confidence interval*
EARS	*Exercise Adherence Rating Scale*
EMA	*Ecological momentary assessment*
FRAME	*Framework for reporting adaptations and modifications-expanded*
gLiFE	*group-based LiFE format*
HAPA	*Health action process approach*
IQR	*Interquartile range*
IRR	*Incidence rate ratio*
ITT	*Intention-to-treat*
LiFE	*Lifestyle-integrated Functional Exercise*
LMM	*Linear mixed model*
MICE	*Multiple imputation by chained equations*
PP	*Per protocol*
RCT	*Randomized controlled trial*
RMSEA	*Root-mean-square error of approximation*
SEM	*Structural equation modelling*
SES	*Socio-economic status*
SMD	*Standard mean difference*
SRMR	*Standardized root-mean-squared residual*
TIDieR	*Template for intervention description and replication*
TLI	*Tucker-Lewis-Index*
WHO	*World Health Organization*

Further dissertation-related publications and conference contributions

Publications

Jansen, C.-P., Nerz, C., **Labudek, S**., Gottschalk, S., Kramer-Gmeiner, F., Klenk, …, & Schwenk, M. (2022). Comparison of the group vs. individually delivered Lifestyle-integrated Functional Exercise (LiFE) program: 12-months follow-up results from the LiFE-is-LiFE non-inferiority trial. [Manuscript submitted for publication]. Robert-Bosch-Hospital, Stuttgart.

Nerz, C., Kramer-Gmeiner, F., Jansen, C.-P., **Labudek, S**., Klenk, J., Becker, C., & Schwenk, M. (2022): Group-based and individually delivered LiFE: Content evaluation and predictors of training response. A dose-response analysis. [Manuscript submitted for publication]. Robert-Bosch-Hospital, Stuttgart.

Hezel, N., Körbi, C., Wolf, M., Adams, M., Jansen, C.-P., **Labudek, S.**, Wolf-Belala, N., Kramer-Gmeiner, F., Nerz, C. & Schwenk, M. (2021). The Lifestyle-integrated Functional Exercise (LiFE) program and its modifications: a narrative review. *German Journal of Exercise and Sport Research*. https://doi.org/10.1007/s12662-021-00770-2

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Conference contributions

Labudek, S., Steckhan, G. M. A., Fleig, L., Warner, L. M., Jansen, C.-P., Kramer-Gmeiner, F., …, & Schwenk, M. (2021, September). *When behaviour becomes a habit: predictors of lifestyle-integrated exercise habits among older adults* [Paper presentation]. 15. Kongress der Fachgruppe Gesundheitspsychologie der Deutschen Gesellschaft für Psychologie, online.

Labudek, S., Fleig, L., Jansen, C.-P., Kramer-Gmeiner, F., Nerz, C., Becker, …, & Schwenk, M. (2021, September). *Sturzprävention beginnt im Kopf?! Effekte des individuellen und*

gruppenbasierten LiFE-Programms auf psychologische Determinanten der Verhaltensänderung [Paper presentation]. 33. Jahreskongress der Deutschen Gesellschaft für Geriatrie e.V., online.

Labudek, S., Steckhan, G. M. A., Fleig, L., Warner, L. M., Jansen, C.-P., Kramer-Gmeiner, F., ..., & Schwenk, M. (2021, August). *When the last intervention session is over: how older adults form and maintain lifestyle-integrated exercise habits* [Paper presentation]. 35th Annual Conference of the European Health Psychology Society (EHPS), online.

Labudek, S., Fleig, L., Jansen, C.-P., Kramer, F., Nerz, C., Becker, C., …, & Schwenk, M. (2019, September). *Wieso? Weshalb? Warum? - Prädiktoren für die Intention älterer Menschen, einen körperlich-aktiven Lebensstil zu führen* [Paper presentation]. 14. Kongress der Fachgruppe Gesundheitspsychologie der Deutschen Gesellschaft für Psychologie, Greifswald, Germany.

Labudek, S., Fleig, L., Jansen, C.-P., Kramer, F., Nerz, C., Becker, C., ..., & Schwenk, M. (2019, September). *Exploring the predictors for older adults' intention to engage in the Lifestyle-integrated Functional Exercise programme* [Poster presentation]. 33rd Annual Conference of the European Health Psychology Society (EHPS), Dubrovnik, Croatia.

Labudek, S., Fleig, L., Kramer, F., Jansen, C.-P., Nerz, C., Clemson, L., ..., Schwenk, M. (2019, April). *Lifestyle-integrated strength and balance training as long-term behaviour change in older adults – psychosocial mechanisms* [Paper presentation]. Jahrestagung der dvs Komission Gesundheit, Hamburg, Germany.

Labudek, S. Fleig, L., Jansen, C.-P., Kramer, F., Nerz, C., Becker, C., Schwenk, M. (2019, January). *Why the Lifestyle-integrated Functional Exercise (LiFE) leads to long-term health behaviour change – theoretical framework and results from a pilot study* [Poster presentation]. MobEx Conference, Trondheim, Norway.

Labudek, S., Fleig, L., Jansen, C.-P., Kramer, F., Nerz, C., Plessner, H., ..., Schwenk, M. (2018, September). *Alltagsintegriertes Kraft- und Balancetraining bei älteren Menschen als Gesundheitsverhaltensänderung* [Poster presentation]. 51. Kongress der Deutschen Gesellschaft für Psychologie (DGPs), Frankfurt, Germany.

Labudek, S., Fleig, L., Jansen, C.-P., Kramer, F., Nerz, C., Barz, C., ..., Schwenk, M. (2018, September). *Die Integration der LiFE-Übungen in den Alltag älterer Menschen als Gesundheitsverhaltensänderung: individuelle und soziale Aspekte* [Paper presentation]. 30. Jahreskongress der Deutschen Gesellschaft für Geriatrie e.V., Cologne, Germany.

Labudek, S., Jansen, C.-P., Kramer, F., Fleig, L., Schwenk, M. (2018, August). *Health behaviour change through lifestyle-integrated functional training: results of a pilot study* [Poster presentation]. 32nd Annual Conference of the European Health Psychology Society (EHPS), Galway, Ireland.

UNIVERSITÄT HEIDELBERG
ZUKUNFT SEIT 1386

FAKULTÄT FÜR VERHALTENS- UND EMPIRISCHE KULTURWISSENSCHAFTEN

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Doctoral Committee of the Faculty of Behavioural and Cultural Studies of Heidelberg University

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Vorname Nachname
First name Family name Sarah Eva Labudek

Datum, Unterschrift
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Appendix A: Author contributions to publications

Table 1

Contributions of each author to the publications I to VI.

Publication	Author position	Study design	Data acquisition	Data analysis	Manuscript preparation
I	1	**SL**, LF	CPJ, CN, **SL**, FKG	**SL**	**SL**, LF, CPJ, FKG, CN, CB, JK, MS
II	2*	FK,**SL**, CPJ, MS	CPJ, CN, **SL**, FK	FK,**SL**	FK,**SL**, CPJ, CN, LF, LC, CB, MS
III	3	LR, FKG, **SL**	LR, FKG, **SL**	LR, FK, **SL**	LR, FKG, **SL**, CPJ, CN, MN, CB, LC, MS
IV	3	MS, CPJ, JK, CB	CPJ, CN, **SL**, FKG	CPJ	CPJ, CN, **SL**, SG, FKG, JK, JD, HHK, LC, CB, MS
V	2	MJW, **SL**	CPJ, CN, **SL**	MJW, **SL**, CPJ	MJW, **SL**, CE, CPJ, CN, LC, CB, MS
VI	1	**SL**, LF	CPJ, CN, **SL**, FKG	**SL**	**SL**, LF, CPJ, FKG, CN, CB, JK, MS

Note. The authors are marked with abbreviations of their first and last name (e.g., Sarah Labudek = SL); the name of the author of this dissertation is marked in bold; * shared first author

Appendix B: Publications of the publication-based dissertation

Publication I

Sarah Labudek, Lena Fleig, Carl-Philipp Jansen, Franziska Kramer-Gmeiner, Corinna Nerz, Clemens Becker, Jochen Klenk, & Michael Schwenk (2021). Applying social cognition models to explain walking duration in older adults: The role of intrinsic motivation. *Journal of Aging and Physical Activity*, 29, 5, 744-752. https://doi.org/10.1123/japa.2020-0296

Manuscript has been published online as Ahead of Print:

Journal of Aging and Physical Activity, **(Ahead of Print)**
https://doi.org/10.1123/japa.2020-0296

Human Kinetics
ORIGINAL RESEARCH

Applying Social Cognition Models to Explain Walking Duration in Older Adults: The Role of Intrinsic Motivation

Sarah Labudek, Lena Fleig, Carl-Philipp Jansen, Franziska Kramer-Gmeiner, Corinna Nerz, Clemens Becker, Jochen Klenk, and Michael Schwenk

This study examined the applicability of the health action process approach (HAPA) to walking duration in older adults and the added value of extending the HAPA by intrinsic motivation. Self-reports from older adults ($N = 309$; $M_{age} = 78.7$, 70–95 years) regarding activity-related intrinsic motivation and HAPA variables were collected at the baseline of a fall prevention intervention study. Walking duration at ≥3 metabolic equivalents of task was measured for 7 days via body-worn accelerometers. Two structural equation models with walking duration as a manifest outcome were specified. In both models, the model fit was acceptable, but intention and planning were not associated with walking duration. Intrinsic motivation was significantly related to most HAPA variables and walking duration. Variance explained for walking duration was $R^2 = .14$ in the HAPA and $R^2 = .17$ in the extended model. For explaining older adults' walking duration, intrinsic motivation, but not HAPA-based intention and planning, seemed to be important.

Keywords: accelerometer, health action process approach, self-determination theory, structural equation modeling

Understanding older adults' health behavior is of high importance in the face of demographic change. The prevention of chronic diseases and the maintenance of functional status and physical independence are important public health interests (Dipietro et al., 2019). Lifestyle factors and individual health behaviors such as physical activity are major factors for healthy aging (Daskalopoulou et al., 2017). It is recommended that older adults (aged 65 years and above) perform multicomponent physical activity consisting of aerobic, muscle-strengthening, and balance exercises (Piercy et al., 2018). However, many older adults experience age-related health problems and chronic conditions (Mannucci & Nobili, 2014) and report poor functional status as a barrier for being physically active (Gellert et al., 2015).

Walking could be a health-beneficial type of physical activity for older adults because it is simple to perform in everyday life, affordable, and relatively safe (Klenk & Kerse, 2019). Nevertheless, walking as an effective type of physical activity for older adults is oftentimes underestimated for two reasons. First, the so-called relative intensity of an activity, that is, the level of exertion during performance in relation to a person's capacity, is higher for older adults than younger persons (Chodzko-Zajko et al., 2009). To address this, the new U.S. guidelines for physical activity (Piercy et al., 2018) additionally use relative intensity in the recommendation of physical activity for older adults. Second, shorter walking intervals might fall below the threshold of a 10-min bout of physical activity recommended by the World Health Organization (2010). Recent studies (Stamatakis et al., 2019) also promote shorter physical activity bouts and incidental activities, that is, any type of activity required while performing personal daily routines, to be health-relevant. Regarding health benefits, walking has been shown to be positively related to cardiovascular biomarker profiles (Klenk et al., 2013) and negatively associated with mortality (Landi et al., 2008). Therefore, walking could be the optimal type of physical activity for older adults in terms of being feasible within their physical capabilities and providing health benefits (Kelly et al., 2014). Additionally, walking is a mandatory motor skill for older adults to master their activities of daily living independently (e.g., preparing meals, personal hygiene) and is associated with health-related quality of life (Groessl et al., 2007). Understanding the underlying modifiable factors that foster or hamper older adults' walking behavior can help to refine and adapt existing theoretical health behavior change models to the target group and help design behavior change interventions.

One of the most comprehensive behavior change models is the health action process approach (HAPA; Schwarzer, 1992, 2008). It has evolved in the tradition of social-cognitive theory (Bandura, 1977), considering self-efficacy and goals as the main predictors of behavior. In the HAPA, self-efficacy, outcome expectancies, and risk perception are predictors of the intention for behavior change. A novelty of the HAPA in comparison with former behavior change models (e.g., theory of planned behavior, Ajzen, 1991) is the inclusion of a volitional phase in order to bridge the so-called intention-behavior gap (Sheeran, 2002). In the volitional phase, self-regulatory strategies such as planning (specifying where, when, and how to perform the intended behavior, Gollwitzer, 1999) and action control (Sniehotta, Scholz, & Schwarzer, 2005) are proposed to help translate the intention into behavior (Rhodes & de Bruijn, 2013; Schwarzer, 2008). A meta-analysis found small-to-medium-sized effects from intention, self-efficacy, and planning on behavior (Zhang, Zhang, Schwarzer, & Hagger, 2019).

Adding self-determined motivation to the HAPA could be a promising approach in order to gain a deeper understanding of the psychological mechanisms associated with older adults' health behavior. Self-determination theory (SDT) describes the conditions under which individuals develop self-motivation (Ryan & Deci,

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2000). The SDT highlights the quality of motivation as opposed to intention defined by the HAPA, which implies the quantity of motivation. Whereas SDT-related motivation explains why individuals are engaging in a certain behavior, the HAPA defines how much effort individuals are willing to invest to enact a certain behavior. The SDT proposes that motivation is controlled or self-determined. That is, individuals could act upon external demands or out of their own interest and choice. More self-determined types of motivation, that is, intrinsic, integrated, and identified motivation, stand opposed to controlled types of motivation, that is, introjected or extrinsic motivation, on a motivation continuum. Intrinsic motivation is defined as arising whenever a task is interesting and fulfilling by itself without being linked to any external outcomes such as (social) reward (Deci, 2004).

In the context of physical activity, intrinsic motivation means that individuals like and enjoy being physically active (Markland & Tobin, 2004). Ferrand, Martinent, and Bonnefoy (2014) showed that highly self-determined older adults report higher levels of physical activity. Intrinsic motivation for physical activity might be particularly beneficial for older adults because of their age-related limited future time perspective and increased attention toward emotionally meaningful goals (Carstensen, Fung, & Charles, 2003; Mikels, Reed, Hardy, & Löckenhoff, 2014). Instead of focusing on potential future positive health outcomes during physical activity, older adults might prefer to be physically active because of direct positive experiences (Gellert, Ziegelmann, & Schwarzer, 2012).

This study aimed to reach a deeper understanding of older adults' health behavior by creating more comprehensive behavior change models (Ziegelmann & Knoll, 2015) in two steps. First, we applied the HAPA to older adults' walking duration, investigating whether the model holds for walking as a health-relevant behavior in older adults.

Second, this study aims to extend the HAPA by intrinsic motivation derived from the SDT. We assume that not only motivation quantity (intention) but also motivation quality (intrinsic motivation) is associated with older adults' walking behavior. Intrinsic motivation will be added to the HAPA, whereas intrinsic motivation will serve as a parallel determinant of behavior, next to intention. Similar to previous studies investigating physical activity in older adults (Arnautovska, Fleig, O'Callaghan, & Hamilton, 2019; Gellert et al., 2012), we choose a structural equation modeling approach for testing the model fit of the HAPA and the extended model.

Regarding the HAPA, we expect self-efficacy, outcome expectancies, and risk perception to predict intention. Furthermore, we expect self-efficacy and planning to predict walking duration. We also expect that planning mediates the relationship between intention and walking duration. Regarding the extended model, we expect that SDT-related intrinsic motivation improves the model fit and contributes unique portions of variance explained in walking duration. In an exploratory analysis, we also examine whether self-efficacy, outcome expectancies, and risk perception not only predict intention but also intrinsic motivation. Furthermore, we expect intrinsic motivation to be a predictor of planning and walking duration.

Methods

Participants

The baseline data from the LiFE-is-LiFE trial (Jansen et al., 2018) were used to test the hypotheses. The falls prevention intervention used in the study is called Lifestyle-integrated Functional Exercise (LiFE; Clemson et al., 2012). Community-dwelling older adults aged 70 years and older who were able to walk at least 200 m without personal assistance were eligible if they had either: (a) one injurious fall or (b) more than one noninjurious fall within the past year or (c) experienced perceived balance decline in the past year and needed 12 s or more to perform the "Timed Up-and-Go" test (Podsiadlo & Richardson, 1991). The exclusion criteria were acute or severe medical conditions and moderate to severe cognitive impairment (Montreal Cognitive Assessment <23; Montreal Cognitive Assessment; Nasreddine et al., 2005). A comprehensive list of all inclusion and exclusion criteria can be found in the study protocol (Jansen et al., 2018).

Procedure

Participants were recruited in two study centers (Network Aging Research, Heidelberg and Robert-Bosch-Hospital, Stuttgart) via letters, flyers, announcements, and public talks. Interested persons needed to respond actively in order to take part in a two-step screening procedure (telephone and in-house). The participants gave informed consent via paper copy at the beginning of the in-house screening. If eligible, the participants underwent a baseline assessment, which took place between June 2018 and May 2019. Questionnaires including social-cognitive variables derived from the HAPA and the SDT were administered by trained interviewers. At the end of the assessment, the participants were equipped with an accelerometer (activPAL4™ micro, PAL Technologies Ltd., Glasgow, Scotland) and instructed to wear it for 7 full consecutive days. The study procedure was approved by both local ethics review boards.

Measures

Questionnaires. The HAPA items were obtained from other studies in the health behavior context (Fleig, McAllister, Chen, et al., 2016; Schwarzer, 2008; Sniehotta et al., 2005) and used in the German version. The participants rated the questions on a 6-point Likert scale ranging from 1 (*not true at all*) to 6 (*totally true*), unless stated otherwise. *Intention* was assessed using the item "I intend to live an active lifestyle." *Self-efficacy* was assessed using two items, one item for motivational self-efficacy, "I am sure that I can integrate more physical activity into my daily routines," and one item for maintenance self-efficacy, "I am sure that I can engage in the LiFE program, even if external factors (e.g., distraction) make it difficult for me." *Outcome expectancies* were assessed using two items, "If I practice LiFE regularly, then I prevent falls" and "If I practice LiFE regularly, then I can continue performing my daily tasks independently in the future." *Risk perception* was assessed via four items: "Compared to other persons of my age and sex, my chances of . . ." (a) ". . . falling . . .," (b) ". . . experiencing a loss of strength . . .," (c) ". . . experiencing a loss of balance capacity . . .," and (d) ". . . experiencing a loss of my physical function . . ." are "much below average" (1), "below average" (2), "average" (3), "above average" (4), or "much above average" (5). *Planning* was assessed using three items, one item for action planning and two items for coping planning, each using the prefix "In the past four weeks, I have made a detailed plan . . . ." Exemplary items for action and coping planning are "how I can integrate more physical activity into my daily life" and ". . . how I can be physically active even if something else comes up," respectively. Based on the SDT (Ryan & Deci, 2000), *intrinsic motivation* was assessed using the German version (Rausch Osthoff, 2017) of the Behavioral Regulation in

Exercise Questionnaire (version 3; Markland & Tobin, 2004). The word "exercise" was replaced by "being physically active." Intrinsic motivation is represented by four items on a scale from 0 (*not true for me*) to 4 (*very true for me*), for example, "I am physically active because it's fun."

Demographic data. Age (in years), height (in cm), weight (in kg), education level (years of education and highest degree), marital status, living situation (alone/together with somebody), number of falls in the last 6 months, and number of morbidities were assessed. Because studies have shown a negative relationship between fear of falling and physical activity in older age (Delbaere, 2004; Sales, Levinger, & Polman, 2017), the short version of the Falls Efficacy Scale International was assessed. Higher scores indicate lower levels of fear of falling.

Walking duration. Walking duration was operationalized as walking duration ≥3 metabolic equivalents of task (METs), that is, only more intensive and longer walking periods were included in the analyses. Walking duration at ≥3 METs was assessed for a full 7 days via the "activPAL4™ micro" (PAL Technologies Ltd., Glasgow, Scotland), a small accelerometer that was attached to the participants' upper right thigh with a piece of medical tape and only needed to be removed during swimming, sauna, or medical examinations. The activPAL has shown to be a valid instrument for measuring older adults' movement (Grant, Dall, Mitchell, & Granat, 2008). We only included cases if complete data from at least two weekdays and the Sunday of the respective week was available (Klenk et al., 2019). The parameter for walking duration at ≥3 METs was derived from raw data. The activPAL detects activities and provides a list of activity changes (e.g., sitting/lying or standing/walking) with a timecode and type of activity, as well as the duration of the activity. For calculating the final score for walking duration at ≥3 METs, Sundays were weighted single whereas the mean of the weekdays was weighted six times.

Data Analysis

Structural equation modeling using R (lavaan package) was performed to analyze the data fit to the HAPA and the extended model. In order to test the models, direct and indirect paths were specified and estimated (Figures 1 and 2). The items for each construct described above served as manifest indicator variables for the respective latent constructs. As depicted in Figure 1, for the HAPA, self-efficacy, outcome expectancies, and risk perception were regressed on intention. Intention and self-efficacy were regressed on planning. Walking duration and planning were regressed on walking duration. We further specified planning as a mediator between intention and walking duration. As depicted in Figure 2, for the extended model, intrinsic motivation was added as an additional variable. As for intention, self-efficacy, outcome expectancies, and risk perception were regressed on intrinsic motivation. Furthermore, we specified a direct path from intrinsic motivation to planning and walking duration. Regarding covariates, we both used other studies (e.g., Arnautovska et al., 2019) as an orientation for the specification of covariates and tested potentially relevant covariates and their association with endogenous model variables. Age, sex, BMI, living situation, and fear of falling were specified as covariates in both models.

Maximum-likelihood estimation was applied to fit the model to the data. The missing data were treated by using the full information maximum likelihood algorithm (Enders & Bandalos, 2001). The model fit was assessed using the Comparative Fit Index (CFI), the Tucker-Lewis-Index (TLI), the root-mean-square error of approximation (RMSEA) and its 90% confidence interval (CI), and the standardized root-mean-squared residual (SRMR). High CFI (>.90)

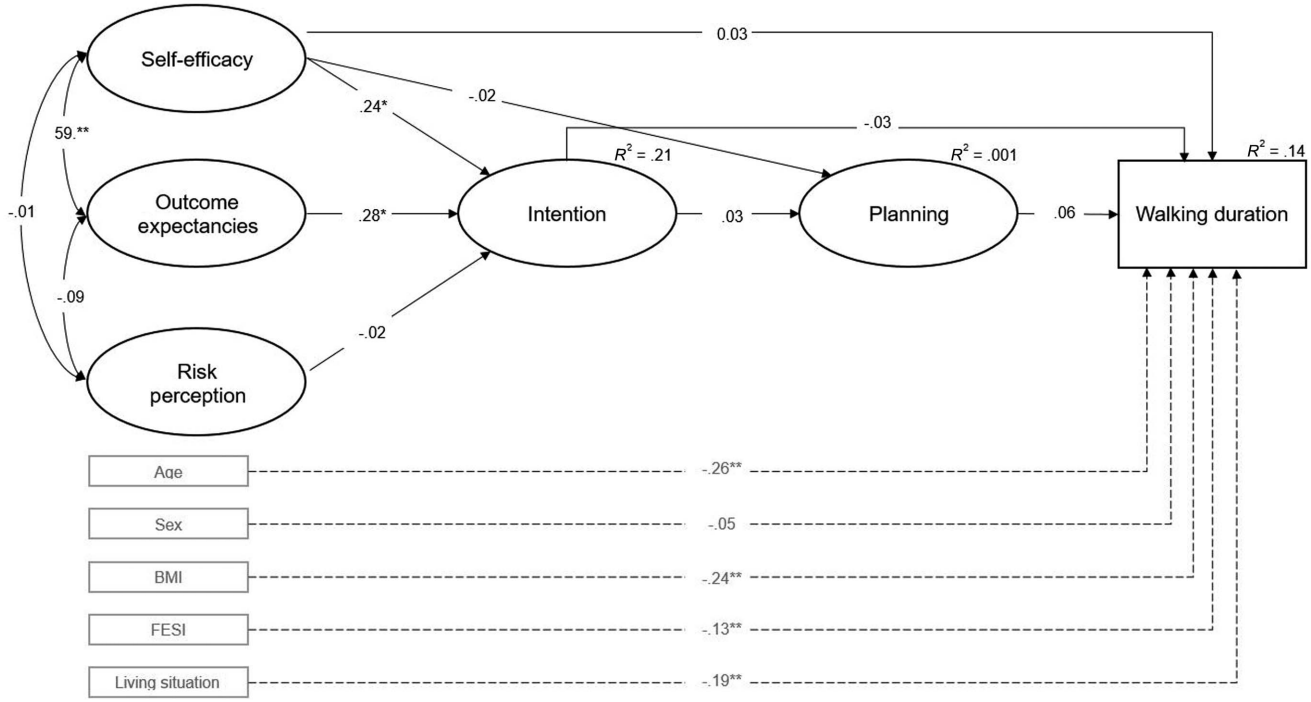

Figure 1 — Structural model for the HAPA, predicting older adults' walking duration ($N = 309$). HAPA = health action process approach; BMI = body mass index; FESI = Falls Efficacy Scale International. *Note.* Fully standardized beta coefficients are reported. Significance levels were $^*p < .05$ and $^{**}p < .001$. Sex = 1 (male), 2 (female).

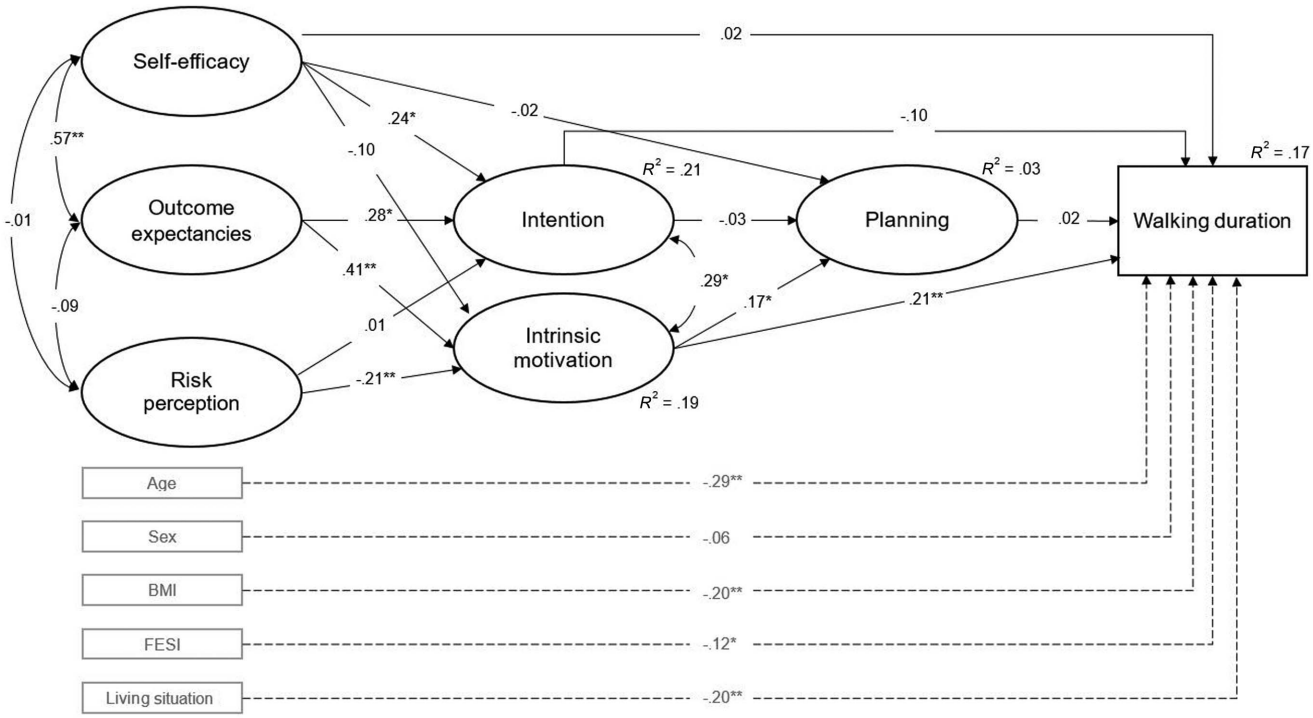

Figure 2 — Structural model for the extended model predicting older adults walking duration ($N = 309$). BMI = body mass index; FESI = Falls Efficacy Scale International (Short FES-I), higher scores indicate lower levels of fear of falling. *Note.* Fully standardized beta coefficients are reported. Significance levels were $*p < .05$ and $**p < .001$. Sex = 1 (male), 2 (female). Living situation = 1 (living alone), 2 (living with another person).

and TLI values (>0.95), as well as low RMSEA (<.06) and SRMR (>.09) values indicate a good model fit (Hu & Bentler, 1999; Steiger, 2007). The RMSEA 90% CI indicates the precision of the RMSEA value; its small range and the proximity of the lower bound to zero indicate a small error (Curran, Bollen, Chen, Paxton, & Kirby, 2003). The HAPA and the extended model were compared against each other by using the Akaike Information Criterion and Bayesian Information Criterion as well as variance explained in walking duration. Lower Akaike Information Criterion or Bayesian Information Criterion values of one model compared with another indicate better model fit (Burnham & Anderson, 2004).

Results

Sample

In total, 309 participants (74% women) completed the baseline assessment. The ActivPAL data were available from 294 participants. Missing data (4.9%) were due to dropout before the baseline completion ($n = 12$) and exclusion because the criterion of having complete data of at least two full weekdays and one Sunday was not fulfilled ($n = 3$). The sample was heterogeneous in terms of age ($M = 78.8$ years, $SD = 5.36$, range = 70–95) and years of education ($M = 13.8$ years, $SD = 4.00$, range = 3–9). Around one-third of the participants (35%) had a high school degree and almost one quarter (23%) had a university degree. Almost half of the participants (45%) were married or in a long-term relationship, 36% were widowed, 13% were divorced or separated, and 6% were unmarried. The participants indicated 2.6 morbidities on average (range = 0–7), most commonly arthritis ($n = 192$) and hypertension ($n = 180$). Concerning falls, 41% of the participants reported to have fallen within the 6 months preceding the assessment, with 75% of the falls being injurious. Few participants used a walking aid (5%).

Descriptive Statistics

Means, standard deviations, intercorrelations, and internal consistencies (Cronbach's alpha) of all latent variables and walking duration are presented in Table 1. The mean values for intention ($M = 5.19$; $SD = 0.85$) and outcome expectancies ($M = 5.18$; $SD = 0.91$) were very high (questionnaire ranged from 1 to 6) on the manifest level.

Structural Equation Modeling

HAPA. All manifest indicators showed significant associations ($p < .001$) with the latent variables (range = 0.62–0.86). The HAPA provided a good fit to the data (CFI = .96, TLI = 0.94, RMSEA = .04 [CI = 0.02–0.05], SRMR = .06). Figure 1 illustrates the standardized parameter estimates for the HAPA. Self-efficacy and outcome expectancies, but not risk perception, were significantly associated with intention. The variance explained in intention was $R^2 = .21$. Self-efficacy, intention, and planning were not associated with walking duration. Regarding covariates, age, BMI, living situation, and fear of falling were negatively associated with walking duration, meaning that participants with higher age, BMI, or fear of falling who lived together with someone showed lower values of walking duration. Planning did not emerge as a significant mediator between intention and walking duration. The variance explained in walking duration was $R^2 = .14$.

Extended model. After adding intrinsic motivation to the model, some of the fit indices slightly declined (CFI = .95, TLI = 0.94, RMSEA = .04, 90% CI [0.03–0.05], SRMR = .06). Figure 2

Table 1 Means, Standard Deviations, Intercorrelations, Covariances, and Variances for Latent Social-Cognitive Variables and Walking Duration

Variable	1	2	3	4	5	6	7
1. Self-efficacy	**0.44**	0.23	0.00	0.23	0.09	–0.01	
2. Outcome expectancies	0.57	**0.37**	–0.03	0.22	0.22	0.03	
3. Risk perception	–0.01	–0.09	**0.26**	–0.01	–0.13	–0.03	
4. Intention	0.40	0.42	–0.01	**0.57**	0.31	0.02	
5. Intrinsic motivation	0.13	0.37	–0.25	0.36	**0.80**	0.20	
6. Planning	–0.01	0.04	–0.04	0.02	0.16	**1.6**	
7. Walking duration[a]							
Factor loadings for the manifest indicators	0.72; 0.62	0.61; 0.77	0.64; 0.80; 0.73; 0.70	1.0	0.75; 0.81; 0.80; 0.67	0.75; 0.84; 0.86	
Mean[b]	4.79	5.18	2.90	5.19	2.83	2.61	37.42
SD[b]	0.83	0.91	0.62	0.85	0.96	1.44	23.59
Range[b]	2.00–6.00	1.50–6.00	1.00–4.50	2.00–6.00	0.00–4.00	1.00–6.00	6.43–205.42
Cronbach's alpha[b]	0.44[c]	0.47[c]	0.81	–	0.84	0.91	–

Notes. Variances are presented in the diagonal in boldface, covariances are presented above the diagonal, and intercorrelations are presented below the diagonal.
[a] Average daily walking duration per day (in minutes) in reference to a week. [b] SD = standard deviation. [c] Pearson correlation (two-item indicator).

Table 2 AIC and BIC Values for the HAPA and the Extended Model

Variable	HAPA	Extended model
AIC	12,396.83	15,698.73
BIC	12,602.16	15,971.26

Note. AIC = Akaike Information Criterion; BIC = Bayesian Information Criterion; HAPA = health action process approach.

depicts the standardized parameter estimates for the extended model. Intrinsic motivation was significantly associated with risk perception, outcome expectancies, planning, and walking duration. The covariance between intention and intrinsic motivation was .32 ($p = .004$). As in the HAPA, age, BMI, living situation, and fear of falling were negatively associated with walking duration, and the mediation effect of planning on the intention–behavior relationship was insignificant. Regarding the comparative fit indices, the HAPA fit the data better than the extended model (see Table 2). In the extended model, the variance explained in walking duration was 3% higher than in the HAPA. The beta coefficients of the extended model were similar compared with a model without covariates, whereas the fit indices were higher (CFI = 1.00, TLI = 1.00, RMSEA = .01, 90% CI [0.00–0.03], SRMR = .03) and the variance explained in walking duration was lower ($R^2 = .05$). Exploratory analysis revealed that, in contrast to correlates of intention, outcome expectancies were positively and risk perception was negatively associated with intrinsic motivation. Furthermore, self-efficacy was not associated with intrinsic motivation.

Discussion

The current study examined the associations between social-cognitive determinants derived from the HAPA, SDT-related intrinsic motivation, and accelerometer-based walking duration in older adults. Based on the assumption that experiencing positive feelings gains importance in older adults (Carstensen et al., 2003), the HAPA was extended by intrinsic motivation serving as an additional variable to capture the nature of physical activity goals in older adults. Overall, the model fit of the HAPA and the extended model were satisfactory, though the intention–planning–behavior relationship could not be shown. In the extended model, intrinsic motivation was revealed to be significantly associated with planning and walking duration of older adults. This contribution is important in order to gain a more comprehensive understanding of walking behavior as a relevant health behavior for the growing population of older adults.

HAPA

Regarding the predictors of intention, self-efficacy and outcome expectancies, but not risk perception, showed to be positively associated with intention. Individuals who had positive expectations about themselves being physically active and the benefits of physical activity itself were more motivated to be active. In line with that, other studies have shown self-efficacy (French, Olander, Chisholm, & Mc Sharry, 2014; Warner et al., 2014; Warner, Wolff, Spuling, & Wurm, 2019) and outcome expectancies (Gellert et al., 2012) to play a decisive role for older adults' intention to engage in physical activity.

For risk perception, we found no association with intention. Our finding indicates that perceiving a relatively high risk of falling and functional decline in older age is not associated with the intention to engage in an active lifestyle. Similarly, Bierbauer et al. (2017) applied the HAPA to self-reported physical activity in 52 older adults (aged 59–74) and found that risk perception was not associated with intention on an intraindividual and interindividual level. Thus, our findings provide further evidence for the fact that positive outcome expectancies and self-efficacy beliefs have a greater impact on participants' motivation than risk perception.

Surprisingly, we did not find any significant associations among social-cognitive determinants of the HAPA and directly assessed accelerometer-based walking behavior. The fact that individuals'

walking durations varied independently of their intention or planning could be due to various reasons. First, on a methodological level, the mismatch between very broad subjectively measured variables (questionnaires) and rather specifically, directly measured walking duration could be a possible explanation. "Engaging in an active lifestyle" as a broad assessment of intention could have led to different interpretations by the participants. Future studies should aim to adapt the HAPA items to the specific accelerometer variables. Second, we used a mini-longitudinal design; that is, older adults were asked to wear the activPAL during the 7 days directly following the assessments of intention and planning. The time lag between the psychological and behavioral assessment might have been too short to expect participating older adults to translate their intentions and plans into actual behavior. Our measurement of walking duration may reflect older adults' current levels of physical activity rather than their intended and planned levels of physical activity.

An alternative explanation may be that planning per se is not a suitable self-regulatory strategy for older adults' walking duration. Supporting this notion, Warner, Wolff, Ziegelmann, Schwarzer, and Wurm (2016) revealed that a planning intervention did not improve older adults' physical activity levels. Their findings are supported by a meta-analysis by French et al. (2014), who concluded that some self-regulatory behaviour change techniques might not be well-accepted by older adults.

The missing associations between HAPA variables and walking duration, as well as the low variance, explained in walking duration, could indicate that other factors might be related to older adults' walking behavior, for example, environmental or biographical factors (Webber, Porter, & Menec, 2010). The fact that participants who lived with somebody else showed lower levels of walking duration is a hint toward the importance of environmental factors, including the social environment, in older adults' walking behavior, which is supported by other studies (Fleig, Ashe, et al., 2016; Schüz et al., 2012; Sniehotta et al., 2013).

Extended Model

The integration of intrinsic motivation into the HAPA as an additional variable next to intention was expected to improve the model fit. This hypothesis was not confirmed because the fit indices indicated a slightly inferior fit for the extended model. Nevertheless, our results revealed that intrinsic motivation was significantly related to walking duration and increased the variance explained by 3%. This means that feelings of intrinsic motivation, for example, experiencing enjoyment and fun during walking, were linked with longer walking duration in our sample. Our results are supported by two studies, by Arnautovska, O'Callaghan, and Hamilton (2017) and Arnautovska et al. (2019). In a qualitative study, 10 out of 20 participants stated that they were physically active because of intrinsic motivators such as enjoyment (Arnautovska et al., 2017). By applying a structural equation modeling approach, Arnautovska et al. (2019) showed that autonomous motivation—including both identified and intrinsic motivation—predicted older adults' self-reported physical activity. In our study, we only used autonomous motivation as an indicator of intrinsic motivation, which showed to be significantly related to walking behavior. Future studies should include a measurement of motivation quality (e.g., Ferrand et al., 2014; Teixeira et al., 2020) to gain a better understanding of how different types of motivation impact physical activity levels.

In the exploratory analysis, we examined whether intrinsic motivation could serve as an additional variable to capture the nature of physical activity goals in older adults. We found that outcome expectancies were positively associated with intrinsic motivation, whereas risk perception was negatively associated with intrinsic motivation.

In our study, older adults who had more positive expectancies about the potential benefits of an active lifestyle showed higher levels of intrinsic motivation. The two items we used for measuring outcome expectancies were related to preventing falls and maintaining independence. Both outcomes relate to and support autonomy in older age. In line with SDT (Ryan & Deci, 2000), expecting the fulfillment of basic needs, such as autonomy, through engagement in physical activity seems to foster intrinsic motivation (Ryan & Deci, 2000). In the field of fall prevention, studies have shown that older adults' intention to take up age-appropriate types of physical activity counteracting their disabilities (e.g., strength and balance training) is driven by positive outcome expectancies rather than by threat appraisal (Yardley, Donovan-Hall, Francis, & Todd, 2007).

In line with that, the results revealed a negative association between risk perception and intrinsic motivation. Our measurement of risk perception related to a potential loss in autonomy (i.e., relative vulnerability to experiencing a fall, functional decline, etc.) and was negatively linked to intrinsic motivation: the higher the relative vulnerability to functional declines, the lower the intrinsic motivation. Risk perception and intrinsic motivation are quite dichotomous constructs by nature, with risk perception being related to feelings of vulnerability (Schwarzer, 2008) and intrinsic motivation being related to feelings of vitality (Ryan & Deci, 2000). Thus, promoting physical activity by addressing positive outcomes instead of focusing on the relative risk for functional decline might be an effective strategy, even in a group of older adults with a confirmed risk of falling or a history of falls.

We assumed that intrinsic motivation could extend the HAPA, implying that intrinsic motivation is a related but distinct factor compared with intention (Hagger & Chatzisarantis, 2007; Wilson & Rodgers, 2004). The significant covariance between intrinsic motivation and intention supports our assumption. Since self-determined motivation has been shown to predict long-term maintenance of physical activity behavior (Teixeira, Carraça, Markland, Silva, & Ryan, 2012) and is relevant for older adults' physical activity levels (Arnautovska et al., 2019; Ferrand et al., 2014), it might be worth considering integrating intrinsic motivation into the HAPA.

Limitations

Two major limitations of our study need to be considered. First, we used the HAPA as a mediation model to examine associations of social-cognitive determinants and walking duration, but did not use a time-lagged design, which is inconsistent with the idea of mediation modeling and leaves aside implicit model assumptions. Nevertheless, investigating the psychosocial determinants, which are related to older adults' walking duration, is important to better understand and promote walking behavior. In future studies, a time-lagged assessment of the HAPA variables and the behavioral outcome would be beneficial.

Second, a variety of other exclusion criteria (e.g., not being able to walk at least 200 m, morbidities such as acute lung diseases or cardio-pulmonary diseases, or cognitive impairment), which were important to ensure the feasibility of the LiFE intervention, expelled a large percentage of older adults and thereby limit the generalizability of our findings.

Implications for Research and Practice

Despite the fact that studies have identified specific drivers of health behavior in older age (Caudroit, Stephan, & Scanff, 2011; Ziegelmann & Knoll, 2015), research on how to predict and improve health behaviors in older adults is still underrepresented. The endeavor to combine social-cognitive health behavior models with SDT-related motivation have mainly been undertaken by using the theory of planned behavior (Arnautovska et al., 2019; Hagger & Chatzisarantis, 2014, 2009). The HAPA, with its volitional constructs such as planning and action control, adds an important factor for explaining physical activity (Scholz, Schüz, Ziegelmann, Lippke, & Schwarzer, 2008; Wolff, Warner, Ziegelmann, Wurm, & Kliegel, 2016; Ziegelmann & Lippke, 2007). Future studies could further investigate the interplay between social-cognitive variables and self-determined motivation in more detail, for example, where to place self-determined motivation and which facets of autonomous motivation to include.

Even though our mini-longitudinal study aimed to understand older adults' walking duration from a theoretical perspective, our results also hold potential implications for the design of interventions. Since researchers have claimed appropriate solutions to foster physical activity in older adults (Fleig, McAllister, Brasher, et al., 2016), providing older adults with opportunities to experience feelings of autonomy, competence, and relatedness—the three basic psychological needs that are assumed to promote self-determined motivation (Ryan & Deci, 2000)—may help to increase their walking duration. Specifically, interventions could consider applying the recently published classification of motivation and behavior change techniques used in SDT-based interventions in order to foster intrinsic motivation (Teixeira et al., 2020).

In this study, we demonstrated that fear of falling as well as living situation were negatively associated with older adults' walking duration. Therefore, future research in older adults should aim for more comprehensive models and consider not only psychosocial but also more distal factors of walking duration or mobility in general (Webber et al., 2010).

Conclusion

The current study extended the HAPA by intrinsic motivation in order to gain a more comprehensive understanding of older adults' walking duration as a health-relevant type of physical activity. Our results point toward the importance of outcome expectancies and self-efficacy beliefs for older adults' intention to engage in an active lifestyle. Intrinsic motivation emerged as the most prominent determinant related to walking duration. Experiencing higher levels of enjoyment and fun was associated with longer walking durations in older adults, which has implications for practice and research. Future studies could continue testing potentially relevant determinants for the growing target group of older adults by applying and combining established health behavior models, as performed in this study.

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Publication II

Franziska Kramer*, **Sarah Labudek***, Carl-Philipp Jansen, Corinna Nerz, Lena Fleig, Lindy Clemson, Clemens Becker, & Michael Schwenk (2020). Development of a conceptual framework for a group-based format of the Lifestyle-integrated Functional Exercise (gLiFE) programme and its initial feasibility testing. *Pilot and Feasibility Studies,* 6:6. https://doi.org/10.1186/s40814-019-0539-x

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Pilot and Feasibility Studies

RESEARCH Open Access

Development of a conceptual framework for a group-based format of the Lifestyle-integrated Functional Exercise (gLiFE) programme and its initial feasibility testing

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Abstract

Background: The Lifestyle-integrated Functional Exercise (LiFE) programme is a fall prevention programme originally taught in a resource-intensive one-to-one format with limited feasibility for large-scale implementation. The aim of this paper is to present the conceptual framework and initial feasibility evaluation of a group-based LiFE (gLiFE) format developed for large-scale implementation.

Methods: The conceptual gLiFE framework (part I) is based on three pillars, *LiFE Activities and Principles*, *Theory of Behaviour Change and Behaviour Change Techniques*, and *Instruction*. The feasibility of gLiFE was tested (part II) within a multimodal approach including quantitative questionnaires measuring safety, acceptability (1 = best to 7 = insufficient), and adherence to the LiFE activities (range = 0–14) as well as a focus group interview. Exploratory self-reported measures on behaviour change including self-determined motivation (range = 1–5), intention, planning, action control, and habit strength (range = 1–6) were assessed pre and post intervention. Data analyses were performed using descriptive statistics and qualitative content analysis.

Results: The development process resulted in a manualised gLiFE concept containing standardised information on gLiFE's content and structure. Feasibility testing: Six older adults (median = 72.8 years, 5 female) completed the feasibility study and rated safety (median = 7.0, IQR = 0.3) and acceptability as high (median = 1, IQR = 1). Participants implemented 9.5 LiFE activities (IQR = 4.0) into their daily routines. No adverse events occurred during the study. In the focus group, the group format and LiFE activities were perceived as positive and important for maintaining strength and balance capacity. Self-determined motivation intention, planning, and habit strength were rated higher post intervention.

Conclusion: The developed conceptual gLiFE framework represents the basis for a gLiFE format with potential for standardised large-scale implementation. Proof-of-concept could be demonstrated in a group of community-dwelling older adults at risk of falling. The public health potential of gLiFE in terms of (cost-)effectiveness is currently being evaluated in a large trial.

Trial registration: ClinicalTrials.gov NCT03412123. Registered on January 26, 2018

Keywords: Older adults, Fall prevention, Functional balance and strength training, Health behaviour change, Habit formation, LiFE, Lifestyle-integrated exercise

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Introduction

Since falls display a major health risk factor in our ageing society [1–3], there is a strong need for increasing accessibility to effective fall prevention programmes. Across different settings, multifactorial training, such as the combination of balance and strength exercises have shown to be most effective in reducing fall rates in older adults [4–8]. However, the "traditional" delivery of balance and strength exercises through structured training often entails low long-term adherence of participants [9–11]. Lifestyle-integrated training was developed as an alternative approach in order to increase long-term adherence through embedding functional exercises into daily life, that is, daily routines are enriched with small low-intensity bouts of activity with the aim to create new activity habits [12–14]. Lifestyle-integrated training has already shown positive effects on fall-related outcomes [12, 15]. For example, the Lifestyle-integrated Functional Exercise (LiFE) fall prevention programme by Clemson et al. [16] recorded greater adherence rates compared to a traditional, structured training. LiFE resulted in a greater increase in motor performance, physical activity and a greater decrease in fall rate compared to the comparator groups. Despite its high potential, LiFE's large-scale implementability is hampered by its resource-intensive one-to-one delivery format within seven home visits [17–19]. A promising solution could be delivering LiFE in a group format (gLiFE).

Three pilot studies on developing a group-based LiFE have already been conducted [20–23]. These group-based concepts were not specifically designed for large-scale implementation. For instance, Gibbs et al. [21, 22] developed a LiFE concept combining four group sessions and one individual session. The individual session aimed tailoring the LiFE activities to participants' individual home environments. While such tailoring is justifiable from a scientific point of view, the additional resources needed conflict with the aim of cost-efficient large-scale implementation. The question is whether tailoring LiFE to a home environment can also be achieved in group sessions, for instance by applying specific teaching methods such as visualisation or group discussions about the individual home environment.

Another study [20] used three trainers to implement group-based LiFE in a sample of 13 young seniors (59–61 years). The high trainer-participant-ratio ensured optimal teaching of the LiFE concept (including one-to-one consultations during group sessions) and a high level of safety during exercising. The high resources needed for this group-based concept may hamper large-scale implementation. The question is whether specific teaching methods and optimal organisation forms may allow for a lower trainer-participant-ratio, without loss of teaching quality and safety. In summary, even though the current group approaches provide a valuable scientific contribution, a group LiFE concept for large-scale implementation needs to be developed and evaluated.

Important features for a gLiFE concept designed for resource-saving public health implementation are an optimised trainer-participant-ratio, implementability into different settings (e.g., community college, community centre), and portable low-cost material allowing quick and easy implementation by group trainers. Further, a standardised trainer's manual could provide comprehensive pathways for teaching both the LiFE strength and balance activities and behavioural change. Such manual is fundamental for standardised large-scale implementation.

Apart from the lack in focus on large-scale implementability, current group-based LiFE formats [20, 24] show room for improving the delivery of behaviour change content. The fundamental aspect of long-term maintenance of the LiFE activities could be reinforced by emphasising on habit formation. Refinements should be made from a large-scale implementation perspective and brake down complex behaviour change theories to comprehensive units. This could enable cost-efficient teaching of programme content by providing for the trainers and therapists (e.g., physical or occupational therapists) a stronger understanding of the psychological underpinnings of the programme.

The aim of this paper is twofold: to present a newly developed gLiFE concept focused on large-scale implementation and building on a sound theoretical framework with a stronger focus on behaviour change (part I) and to present results of an initial feasibility testing of this new gLiFE concept (part II).

Part I: conceptual framework of gLiFE

The conceptual gLiFE framework was developed building on existing LiFE concepts [20, 24] and theories and methods on group learning. Specific behaviour change theories were used to refine the theoretical framework in order to support long-term maintenance of LiFE. gLiFE was developed (part I) and initially tested in a feasibility study described in this paper (part II). The cost-effectiveness evaluation of gLiFE within a non-inferiority trial (grant no. 01GL1705A-D) comparing gLiFE to LiFE is currently being carried out and not described in this paper. The study protocol is described elsewhere [17].

gLiFE development process

The development process was based on the UK Medical Research Council (MRC) guidelines [25] which propose four steps (development, feasibility and piloting, evaluation, implementation) for the design of complex interventions. An interdisciplinary team of experts in exercise science, health and social psychology, occupational therapy, geriatric medicine, physiotherapy, health economy, and gerontology took part in the development of the gLiFE concept. In addition, 11 users aged 67 to 90 were involved to test and evaluate possible forms of gLiFE during the development process.

Based on previous LiFE studies [18, 19, 24], the number of seven group sessions and sequence of gLiFE activities was determined. In order to compensate for a lower trainer-participant-ratio, theories [26, 27] and methods [28–32] on group learning informed the design of the framework conditions including group size [31], organisational setting [28] and structure [29–31]. The way of instructing gLiFE was informed by the Social Learning Theory [27] which proposes role models and reinforcement as core elements of the group learning setting. Through group activities and discussions, gLiFE fosters group cohesion [26] in order to keep participants engaged and motivate them to practice LiFE.

The development process resulted in a manualised gLiFE concept containing relevant information on content and structure of each gLiFE session. Table 1 provides an overview of the modifications undertaken in gLiFE compared to the individually delivered LiFE.

Conceptual gLiFE framework

The conceptual gLiFE framework is based on two main pillars, *LiFE Activities and Principles* and *Theory of Behaviour Change and Behaviour Change Techniques* (Fig. 1). The third pillar, *Instruction*, predefines how the contents of gLiFE are delivered. The subcategories *Methods*, *Organisational Setting*, and *Materials* contain more detailed information on how to carry out gLiFE.

Pillar I: LiFE activities and principles

The content of the LiFE programme, the LiFE activities and principles from Clemson et al. [16, 33] were used as a foundation for gLiFE. LiFE contains 14 activities addressing static and dynamic balance, lower limb strength, and overall physical activity. These activities are effective for the target group of fall-prone older adults but at the same time performable during daily activities. Teaching the LiFE principles (Fig. 1) alongside the LiFE activities enables participants to integrate the activities into their daily routines and manage their training independently and sustainably [24].

Table 1 Similarities and differences between LiFE and the newly developed gLiFE format

	LiFE	gLiFE
Aim	Improve balance and lower limb strength, increase physical activity, decrease risk of falling; long-term sustainability of the LiFE activities through habit formation and self-empowerment	
Idea	Create new movement habits through linking LiFE activities to specific daily situations	
Structure	Up to seven home visits of 1 hour; explain the LiFE principles during the first home visit, introduce the LiFE activities flexibly (1–2 balance/strength activities per session)	Seven sessions of 2 hours; introduction of LiFE activities in a predetermined order
Content	LiFE principles, balance and strength activities, adapt activities to own training progress (upgrading)	
	Planning	Planning (implementation intentions), theory-based behaviour change units, group discussion
Teaching	Foster autonomy in choosing daily situations for implementing the LiFE activities; tailor and adapt the LiFE activities throughout the intervention phase, visualisation	
Instruction	Flexible procedure	Detailed curriculum (gLiFE concept), trainers follow teaching methods (e.g., repetition and variation) and BCTs[a], different organisational settings (mostly circle of chairs)
Materials	LiFE assessment tool (assessment of level of difficulty in movement execution), LiFE participant's manual	
	Activity counter (recording the number of performed activities), activity planner (detailed planning on when, how, and where the activities can be implemented), daily routine chart (identify suitable opportunities for implementing LiFE activities into daily routines)	Workbook (including activity counter and activity planner), flipchart, posters, cardboard boxes, and towels
Setting	Participant's homes	Public room
Trainer-participant-ratio	1:1	1:6 (two trainers in a group of up to twelve participants)

[a]Behaviour Change Techniques (BCTs) are the smallest identifiable parts of behaviour change interventions, mapped by Michie et al. (2011)

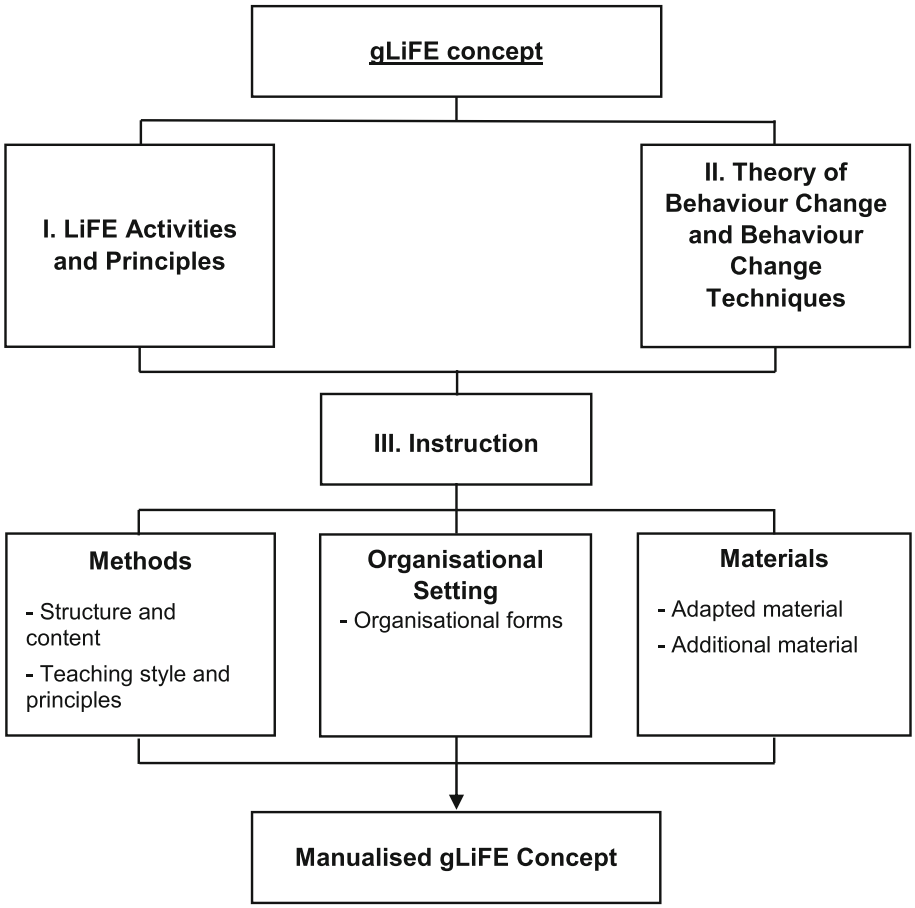

Fig. 1 Conceptual gLiFE framework. The first pillar *LiFE Activities and Principles* is based on the original LiFE activities and principles which are "reducing your base of support", "shifting weight and moving to the limits of stability", "stepping over objects" [33] for balance and "increase the number of times that you use a muscle", "move slowly – this can make the muscles work harder", "use fewer muscles to move the same weight", and "increase the amount of weight you have to lift or move" [33] for strength. The second pillar *Theory of Behaviour Change and Behaviour Change Techniques* is novel to gLiFE and provides a theoretical underpinning using the Health Action Process Approach, habit formation theory, and Self-Determination Theory as well as a conceptualisation and description of gLiFE's components with the help of the BCTs. The third pillar *Instruction* consists of methods, organisational setting and materials and describes the way of delivering gLiFE. In the manualised gLiFE concept, a detailed curriculum is provided in order to teach gLiFE in a standardised manner

In LiFE, there is no predefined order along which the LiFE activities should be introduced. Experiences from the user involvement showed that teaching the LiFE activities to a group requires a different approach. Therefore, a standardised order of introducing LiFE activities over the course of the seven sessions was developed (Fig. 2). The order of LiFE activities was determined based on user preferences evaluated in a previous study [19]. In gLiFE, the most popular LiFE activities which are easy to integrate (e.g., sit to stand) are introduced during the first group sessions. More complex activities (e.g., stepping sideways) and more challenging activities (e.g., one-leg stand) are introduced later. Gradually increasing the complexity of content taught over the course of the group sessions aims to prevent overtaxing participants and ensures positive learning experiences.

Pillar II: theory of behaviour change and behaviour change techniques

LiFE goes beyond traditional fall prevention programmes; it aims for the establishment of new movement habits through integrating exercises into daily routines [24]. The theoretical underpinning of gLiFE was formed using the existing conceptual model of LiFE [24, 33], habit formation theory [34, 35], and the pilot study of Fleig et al. [20] which used the Health Action Process Approach (HAPA) [36, 37]. Additionally, we used the Self-Determination Theory [38].

Habit formation theory describes the habit formation process within three subsequent stages: intention formation, action initiation and habit formation [39]. After deciding to act, a person needs to apply self-regulatory strategies in order to act out the behaviour. After various

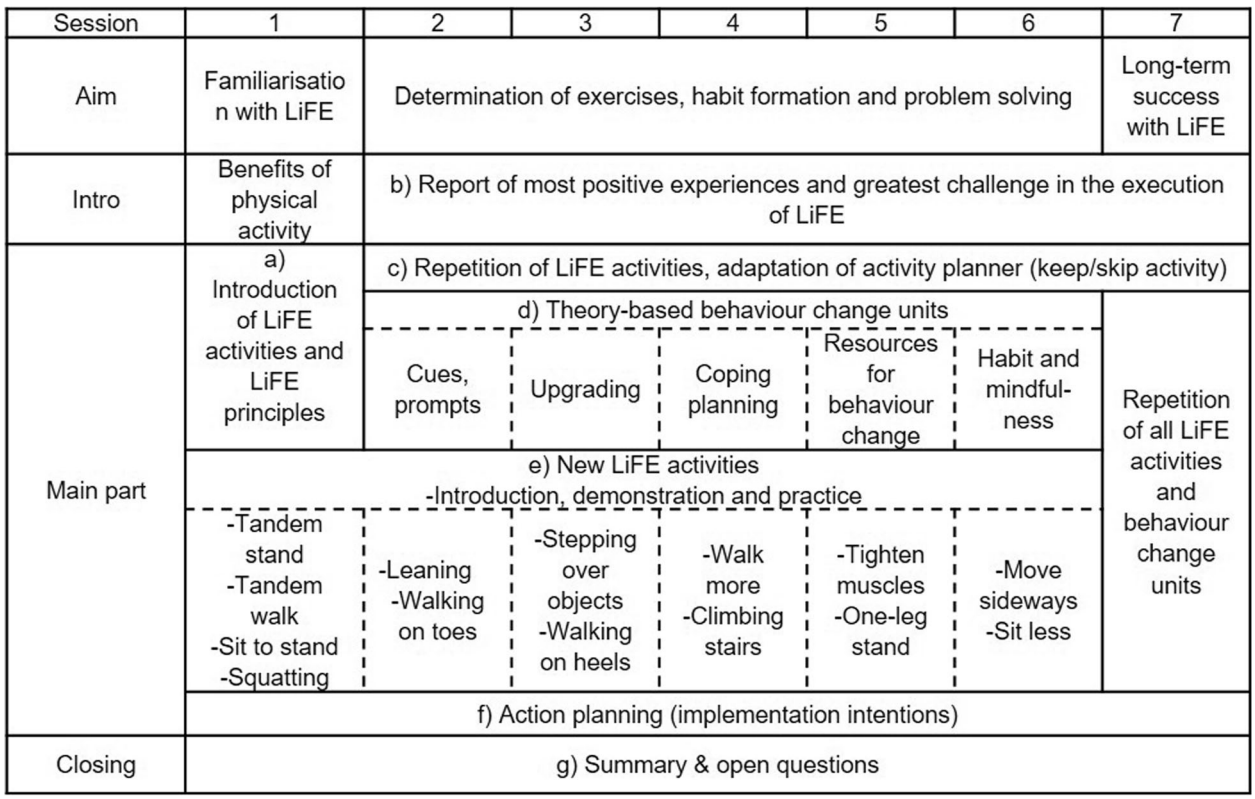

Fig. 2 (**a**) to (**g**) refer to the chronological introduction of categories in the text. The LiFE Activities and Principles (pillar I in the conceptual gLiFE framework) are addressed in section (**a**), (**b**), and (**e**). Theory of Behaviour Change (pillar II) is addressed in section (**d**) and Behaviour Change Techniques (pillar II) infuse all gLiFE sessions. gLiFE contents are matched with the BCTs in Table 5 in Appendix 1

repetitions of the behaviour in the same context, the association between the context and the behaviour strengthens until the execution becomes automatic (habitual). gLiFE makes use of this mechanism so that participants perform the LiFE activities habitually in the long run.

The HAPA served to enrich habit formation theory because of its emphasis on the motivational and volitional factors during behaviour change. These factors are particularly relevant during the early stage of behaviour change and could provide additional support for beginners. For example, the planning procedure was specified by using implementation intentions [40]. Instead of stating how, when and where to perform the LiFE activity, participants explicitly formulate a whole sentence in which the situational cue is followed by the LiFE activity (e.g., "If I brush my teeth, then I do the tandem stand"). This novelty may promote habit formation better since entering the situation could bring the LiFE activity into mind automatically. Next to habits, intrinsic motivation is another beneficial factor for long-term maintenance physical activity behaviour [41]. Self-Determination Theory [38] proposes intrinsic motivation to arise alongside the fulfilment of three psychological needs, autonomy, competence, and connectedness. gLiFE fosters these needs through self-empowering participants to manage their training independently and become their own LiFE trainer. In contrast to LiFE, gLiFE has the potential to foster connectedness particularly through the presence of peers.

The LiFE programme already used the habit formation theory, and while participants' action plans were devised to incorporate elements of habit reforming, it was only taught to trainers not participants. However, increasing participants' awareness on the psychological factors which can promote behaviour change may increase intervention success. Therefore, the Behaviour Change Technique (BCT) Taxonomy v1 [42] was applied to map the used theories into intervention practice and short theoretical units of 10–15 min length (Fig. 2). This step is essential for large-scale implementation because it enables facilitators without special training in psychology to teach complex theoretical concepts.

The BCTs drawn from Fleig et al. [20] were revised and adapted to the gLiFE concept and the novel contents were categorised by two of the authors (SL, LF). Next to the LiFE-inherent BCTs (e.g., demonstration of the behaviour, BCT 6.1.; behavioural practice/rehearsal, BCT 8.1.), social reward (BCT 10.4.) was added to promote habit formation through positive reinforcement in

the group setting. Information about health consequences (BCT 5.1.) was added to foster positive outcome expectancies. A detailed form of delivery [43] of all applied BCTs and their link to the used theories is described in Table 5 in Appendix 1.

Pillar III: instruction

A transparent description of how to teach LiFE in a group setting aims to facilitate dissemination of gLiFE and ensures intervention fidelity. Determining methodological standards is essential to streamline content and delivery of gLiFE.

The gLiFE framework draws on experiences and theories from previous studies [19, 20, 23, 33] refined and upgraded for our purposes. Teaching methods aimed to deliver the two main pillars of gLiFE as effective as possible in a group setting. For the purpose of large-scale implementation, gLiFE is designed for any room equipped with chairs. Instruction includes the following subcategories: methods, organisational setting, and applied materials (Fig. 1).

Methods gLiFE was conceptualised for groups of up to 12 participants following recommendations on group size [31] and previous group-based LiFE pilot studies [23]. Based on group simulations and findings from Li and colleagues [23], we considered two trainers—one main and one co-trainer—as necessary for effective delivery and safety. The main trainer explains and demonstrates the theoretical and practical content, leads group discussions, and acts as the main contact person for participants. The co-trainer demonstrates and corrects the activities, documents, helps to shape in discussions, and ensures safety and support, particularly for functionally impaired participants.

Each gLiFE session follows a predefined order which is listed in Fig. 2.

To teach the LiFE activities and the behaviour change theory in the group setting, (motor) learning principles such as *structuring and progression* [44] (BCT 8.7. graded tasks), *repetition and variation* [44] (BCT 8.1. behavioural practice/rehearsal), and *clarity* [45] (BCT 4.1. instruction on how to perform the behaviour) are applied. *Structuring and progression* is based on established learning guidelines and methods such as *from easy to difficult* [29, 30]. For example, stepping over objects is first taught with a flat piece of paper on the floor in order to prevent slips or trips, later on with a cardboard box in order to simulate a real obstacle. The principle *repetition and variation* includes a repetition of previous LiFE activities.

Based on motor learning theory, trainers use a deductive approach for introducing the LiFE activities [29, 46], i.e., predefined and detailed instructions to ensure a correct movement execution of the LiFE activities (BCT 2.2. feedback on behaviour). Several teaching techniques including frontal teaching (BCT 9.1. credible source), group discussions, open questions, and group work [47] are employed in order to teach gLiFE effectively (Table 5 in Appendix 1).

The second pillar is taught using specific methods such as a flipchart to collect participants' suggestions for daily situations to implement the LiFE activities. Through the presence of peers, participants get a larger repertoire of potential daily situations and are able to support each other in programme implementation. To compensate for the missing home visits, participants visualise themselves performing specific LiFE activities in their home environment (BCT 15.2. mental rehearsal of successful performance). Visualisation as a mental technique [48] has been applied in LiFE [33] and was successfully used in previous physical activity interventions [49, 50] and has been positively evaluated in a meta-analysis [51].

Organisational setting State-of-the art organisational forms for group teaching and group exercising [28] were chosen to facilitate communication of group members and trainers while ensuring safety during exercising (Table 6 in Appendix 2). This includes a circle of chairs with all participants and trainers facing each other. Chairs allow hold and support if needed. Specific organisational settings are used for specific activities (Table 6 in Appendix 2). For instance, for teaching the activity "walking on toes", participants walk along a wall. This type of practice can easily be transferred to the home environment, e.g., walking in a hallway, with a high level of safety.

Materials The original materials of LiFE such as the LiFE assessment tool, activity planner, and activity counter [33] served as a basis for the design of the gLiFE materials (Table 1). Participants receive a workbook containing a modified activity planner which simplifies the planning and self-monitoring procedure (BCT 2.3. self-monitoring of behaviour). It combines the activity planner with the activity counter because the paperwork has been reported to be tedious in former studies [18, 20, 23]. Since the LiFE activities are identical in LiFE and gLiFE, participants receive the German version of the LiFE participant's manual [52].

In addition, specific materials for teaching LiFE in a group were developed such as a poster with the LiFE principles, posters displaying the different LiFE activities as well as different aids for practicing the correct movement execution (e.g., a poster with a kitchen shelf which we attached to the wall to practice standing on toes). The ideas from the group discussions are collected on flipchart.

Methods

Part II: feasibility testing

A feasibility study (ClinicalTrials.gov, NCT03412123) was conducted to test the proof-of-concept of gLiFE. This included an evaluation of the three pillars of the gLiFE concept, i.e., the LiFE activities (pillar I), a pre-post assessment of psychological components related to behaviour change (pillar II) and gLiFE's instruction (pillar III).

Design and setting

A single-group feasibility study was conducted from January to March 2018, including seven weekly gLiFE sessions. A multimodal pre-post assessment approach including quantitative and qualitative feasibility measures as well as exploratory self-reported psychosocial measures was applied.

Population

A sample of eight community-dwellers aged 65 years and older was envisaged. They were recruited from a list of former participants of studies conducted at the Network Aging Research in the field of ageing and physical activity. To avoid interferences with our study, we chose participants whose former study participations were at least more than 6 months ago. Eligible participants had to be able to reach the study centre independently and willing to sign written informed consent. Those with an unstable or terminal medical condition, cognitive impairment according to the CogTel questionnaire [53], or severe visual or hearing impairment were excluded.

Procedure

Baseline characteristics and outcome measures were assessed prior to group participation at the Network Aging Research (Heidelberg University, Germany). One week before the first group session, participants received the LiFE participant's manual [52]. The gLiFE sessions were delivered in accordance with the developed gLiFE concept (Fig. 2) by an exercise scientist as main trainer (FK) and a psychologist (SL) as co-trainer. The duration of gLiFE sessions ranged from 1.5 to 2 hours. After the intervention phase, outcome measures were obtained.

Descriptive measures

Participant characteristics including sex, age, BMI, educational level (highest degree of education), physical activity status (below or above 150 min of moderate to vigorous activity per week in the past 12 months [54]), pain level in the past 4 weeks (6-point Likert scale, no pain to very high pain), impact of pain on activities of daily living, fall history in the past 12 months, fall injuries, perceived fall risk (below average to above average), number of comorbidities, and functional strength (5-chair-rise test [55]) and balance (8-level balance scale [16]) were assessed at baseline.

Outcome measures

The outcome measures included quantitative and qualitative feasibility measures.

Quantitative feasibility measures

The following quantitative outcomes were assessed using a questionnaire previously developed for evaluating LiFE [19].

Perceived safety and adverse events Participants rated their perceived feeling of safety during the execution of LiFE activities on a 7-point Likert scale. Participants documented adverse events including pain, falls, and injuries during the intervention phase.

Adherence We assessed the average number of participants per session. Based on other LiFE studies [19], participants reported the number of their implemented LiFE activities and weekly frequency of practice as an additional measure of adherence.

Acceptability Participants rated the overall acceptability of gLiFE from 1 (very good) to 6 (insufficient); one question on whether the participants would recommend gLiFE to a friend (yes/no); participants rated (a) the perceived helpfulness of LiFE activities for improving balance, strength, and physical activity; (b) the perceived difficulty of LiFE activities and of upgrading; and (c) the implementability into daily life on a 7-point Likert scale from 1 (not at all) to 7 (very much).

Qualitative feasibility measures

A semi-structured focus group interview was conducted to gather further information about structure and content of gLiFE, competence of trainers, used materials, implementation of the LiFE activities and ideas for improving gLiFE. The focus group was administered by an independent researcher not involved in the intervention.

Exploratory self-reported psychosocial measures on behaviour change

To get an initial indication on the psychological processes related to behaviour change in gLiFE, selected variables were assessed prior to and post intervention. Response formats of the applied questionnaires were 6-point Likert scales ranging from 1 (completely disagree) to 6 (totally agree), unless stated differently.

Intention to practice the LiFE activities and to realise an active lifestyle was assessed using two items (Table 2).

Self-determined exercise motivation was assessed using the Behavioural Regulation in Exercise Questionnaire (BRE-Q3 [56]). The questionnaire consists of 24 items measuring six different motivational qualities with four items ranging from 0 (does not apply to me at all) to 4 (totally applies to me). The Relative Autonomy Index (RAI) is a weighted score indicating the level of self-determined motivation. Higher scores indicate higher self-determined motivation.

Action and coping planning was assessed using four items according to Sniehotta et al. [57] which were adapted to study purposes.

Action control was assessed using two items according to Sniehotta et al. [57].

Habit strength was assessed using four items of the Self-Report Behavioural Automaticity Index [58]. The four items were adapted to the LiFE activities, e.g., "*The LiFE activities are something I do automatically*".

Data analysis

Participant characteristics are reported as number of participants (*N*), percentage (%), median, and interquartile range (IQR), as appropriate. Number of implemented LiFE activities and frequency of practice are also reported as median and IQR. Likert scale questionnaires are reported as median and IQR. We used SPSS 24.0 (IBM, Armonk, NY, USA) to calculate descriptive results. Focus group recordings were transcribed and subsequently analysed using an inductive qualitative content analysis [59]. Two authors (FK, SL) independently familiarised themselves with the interviews and built three categories in three subsequent steps. The authors agreed on a set of codes and applied them to the whole manuscript. Subsequently, both authors created a coding network using NVivo11 (QRS International, Australia).

Results

Seven participants were willing to take part in the study; one participant withdrew due to health problems, six participants (median = 72.8, IQR = 2.8, 5 female) completed the intervention (for the flow diagram, see Fig. 3 in Appendix 3). The sample was heterogeneous with respect to education level, physical activity level, perceived pain, fall history, and comorbidities (Table 3). Participants reported to perceive their risk of falling as being average compared to other persons their sex and age. However, according to the cut-off values for functional strength measured by the 5-chair-rise test [60], our sample had a high risk of falling. Participants' balance measured by the 8-level balance scale is comparable to previous studies [16]. Participants did not report any major acute health conditions.

Implementation of the gLiFE intervention

gLiFE was delivered as planned including structure of each group session (part I, Fig. 2). Trainers perceived the lower trainer-participant-ratio as feasible and safe. Applied teaching techniques and organisational settings could be carried out as intended (part I, Table 5 in Appendix 1 and Table 6 in Appendix 2). Switching organisational forms was uncomplicated. However, finding individual training levels for all participants using the LiFE assessment tool in group setting was challenging because trainers had to rate and supervise all participants simultaneously. Documentation of action plans (implementation intentions) with the help of the modified activity planner worked well in the group setting. Trainers perceived the designed low-cost material such as card boxes for stepping over objects as helpful and safe.

Quantitative feasibility measures

The majority of participants reported they felt "very safe" while performing the LiFE activities (Table 4). No adverse events were reported. On average, five out of six participants attended each session. Most of

Table 2 Exploratory self-reported measures on behaviour change (*N* = 6)

Construct (number of items)	Items (example)	T1 median (IQR)	T2 median (IQR)
Intention (2)	I intend to live an active lifestyle.	6.0 (0.1)	6.0 (0.3)
Self-determined exercise motivation (24)	I exercise because it's fun.	3.5 (1.4)	4.0 (0.6)
Action and coping planning (4)	During the last week, I have made a detailed plan regarding the situations in which to perform the LiFE activities.	4.5 (1.9)	5.0 (1.4)
Action control (2)	During the last week, I watched carefully to perform the LiFE activities as I planned to.	4.3 (1.4)	3.0 (0.5)
Habit strength (4)	The LiFE activities are something I do automatically.	3.4 (1.3)	4.5 (2.0)

Response format: Intention, action and coping planning, action control and habit strength were assessed on a 6-point Likert scale (1 "completely disagree" to 6 "totally agree") and self-determined exercise motivation was assessed on a 5-point Likert scale (0 "does not apply to me at all" to 4 "totally applies to me"). T1 was assessed before gLiFE intervention, T2 was assessed post intervention

Table 3 Descriptive characteristics of the study population ($N = 6$)

	N	%	Median (IQR)
Sex			
Female	5	83.3	
Male	1	16.7	
Age			72.8 (2.8)
BMI			28.0 (2.3)
Highest degree of education			
Secondary school	3	50.0	
University of applied science	2	33.3	
University degree	1	16.7	
Physical activity (times per week)			
None	2	33.3	
1	3	50.0	
> 1	1	16.7	
Pain level (past 4 weeks)			3.0 (2.0)
Impact of pain on ADLs			3.0 (1.5)
Falls (last 12 months)			
None	3	50.0	
1	1	16.7	
2	1	16.7	
> 2	1	16.7	
Fall injury (last 12 months)			
Yes	1	16.7	
No	5	83.3	
Perceived fall risk			2.5 (1.0)
Comorbidities (number)			2 (1.5)
Functional status			
5 CRT			12.4 (4.2)
8 LBS			5.0 (0.8)

Physical activity level is defined as times of physical activity of moderate to vigorous intensity per week. Pain level is defined as 0 (no pain) to 5 (very high pain). Impact of pain on activities of daily living (ADL) is defined as 1 (never) to 5 (very). Perceived fall risk was defined as 1 (much below average) to 5 (much above average). 5 CRT = 5-chair-rise test; 8 LBS = 8-level balance scale

the participants reported that they had implemented more than half of the LiFE activities over the course of the programme for 5 days per week (Table 4). Overall acceptability of gLiFE was "very good" and everyone would have recommended it to a friend. Participants rated gLiFE as (a) "helpful" for improving balance, strength, and physical activity; (b) "low" with respect to perceived difficulty and upgrading of the LiFE activities; and (c) "rather easy" to implement into daily life (Table 4).

Qualitative feasibility measures

Five of six participants took part in the semi-structured interview; one participant cancelled due to illness. Qualitative content analysis resulted in three categories: *Format*, *Implementation of Activities*, and *Perceived Intervention Effects*. Format refers to participants' opinions on the group setting, safety, trainers, materials, and LiFE activities as well as their delivery; implementation of activities refers to habit formation and cues/prompts to which the LiFE activities can be linked; perceived intervention effects refers to physiological and psychosocial changes related to LiFE.

Format

Group setting Participants reported that the atmosphere within the group was "very good" (female, aged 73). Participants "felt very comfortable, also with the trainers" (female, aged 70). One participant would have preferred a larger group size. One participant "found it nice to get to know the activities in the group setting. It showed that being a 'lone warrior' is not as effective and motivating as being in a group" (female, aged 68).

Safety In line with the quantitative results, participants reported they felt very safe during the gLiFE sessions. The trainer-participant-ratio was perceived as "good" (female, aged 68) and participants reported they felt safe "having both trainers on [their] side" (female, aged 73).

Delivery of gLiFE content It was stated that the gLiFE sessions had a "good and systematic structure" (female, aged 73) and that the structure was "enjoyable and thoughtful" (female, aged 73). One participant remarked that "the balance between theory and practice was suitable and appropriate for [their] age" (female, aged 78). Participants found the repetition of LiFE activities in the beginning of each session was necessary and useful ("I found the repetitions very nice and I recognised whether I had done the exercises correctly or not", female, aged 70) and that visualisation were a helpful strategy for embedding the LiFE activities into daily routines. Participants emphasised that the movement corrections were "supportive" (female, aged 73), and "important" (female, aged 73); one-to-one corrections were appreciated ("It has been implicitly corrected without anyone being exposed to the group", female, aged 78).

LiFE activities Participants reported they felt highly autonomous in choosing their LiFE activities ("I can choose those activities for myself which are effective for me and I can benefit from them, because I have a high risk of falling", female, aged 78).

Material Participants valued the manual as an additional aid next to the explanations during sessions ("If I didn't

Table 4 Quantitative results of the feasibility study ($N = 6$)

gLiFE component	Item	Median (IQR)	Range
Safety	Did you feel safe in the group while doing the LiFE activities?	7.0 (0.3)	1 (very unsafe) to 7 (very safe)
Adherence			
Implemented activities (#)		9.5 (4.0)	0 (none) to 14 (all)
Freq. of perf. (days/week)		5.2 (2.1)	0 (never) to 7 (daily)
Acceptability			
Overall grade	Overall, what grade would you give gLiFE?	1.0 (1.0)	1 (very good) to 6 (insufficient)
Helpfulness to increase:	Do you feel that the activities are useful to improve your balance, strength or physical activity?		1 (very useless) to 7 (very useful)
Balance		6.5 (1.0)	
Strength		6.5 (1.0)	
Physical activity		6.0 (0.8)	
Difficulty of upgrading	How easy or difficult was it for you to adapt the LiFE activities to your own training progress?	5.5 (1.3)	1 (very difficult) to 7 (very easy)
Integration into daily life	How easy or difficult was it for you to integrate the LiFE activities into your daily life?	5.5 (2.3)	1 (very difficult) to 7 (very easy)

Freq. of perf. Frequency of performance

know exactly how to execute one LiFE activity, I used the manual and looked it up", female, aged 68). In contrast, participants reported that working with the activity planner was too complex and unhandy ("I only used it at the beginning, that was too cumbersome and complex for me", female, aged 70).

Implementation of LiFE activities

Habit formation Participants valued action planning as a central and helpful element for the implementation of the LiFE activities into daily life ("Planning in which daily situation I execute the LiFE activities helped me to carrying out the activities […]. They remind me of doing the exercises in these situations", female, aged 70). Participants described daily routines in which they could "implement the one or the other LiFE activity the whole day" (female, aged 73). Participants remarked that some new movement habits arose during intervention phase ("I do certain LiFE activities every morning and evening in the bathroom", female, aged 70).

Cues/prompts Participants described that situational cues were helpful to remember performing the LiFE activities ("That makes a lot of sense and it is good for reminding, it caused a wow-effect", female, aged 68). However, some participants remarked that they did not always perform the LiFE activities in the situation they chose during gLiFE sessions ("I did not do it in specific situations. Sometimes I just did it when it occurred to me", female, aged 70).

Perceived intervention effects

Physiological effects Some participants described reduced pain related to gLiFE participation. In contrast, one participant "[…] felt pain while standing up from a seated position and walking on heels" (female, aged 70). One participant at high risk of falling remarked that she felt "much safer while walking on the street. [She] did not fall since Christmas, [She was] really proud of [her]-self" (female, aged 78).

Psychosocial effects Participants stated that taking part in gLiFE evoked a feeling of fitness, vitality, and a general sense of well-being: "The LiFE activities [were] very helpful. I really feel a sense of well-being in my body. I feel more relaxed, relieved and less or no more pain" (female, aged 73). All participants planned to continue LiFE because of its relevance and necessity ("It would be stupid not to continue with the LiFE activities. I would only harm myself", female, aged 78).

Exploratory self-reported measures on behaviour change

Descriptive results showed that intention to follow an active lifestyle stayed high, whereas self-determined motivation measured by the RAI increased during intervention phase, which may suggest higher levels of intrinsic motivation after gLiFE than before (Table 2). Action and coping planning and habit strength slightly increased over the course of the intervention whereas action control decreased.

Discussion

We successfully achieved our study aims in terms of developing (part I) and initially testing (part II) a new gLiFE concept designed for large-scale implementation. To the best of our knowledge, this is the first gLiFE concept specifically tailored towards the purpose of a resource-saving dissemination within public health approaches.

Part I: Development of the gLiFE concept

Building on previous group-based LiFE concepts, our proposed gLiFE concept has several novel features with respect to large-scale implementation including lower trainer-participant-ratio, flexible implementability into different settings, low-cost materials, and a manualised concept designed to standardise structure of content and teaching procedure. We used the established MRC guidelines for developing the gLiFE concept. There are also other frameworks, such as FRAME [61] in order to refine interventions which could be used in further studies.

Development process

The MRC guidelines recommend an iterative approach including multiple improvement cycles when developing complex interventions. Having involved users at an early stage of the gLiFE development process allowed us to test initial ideas on the organisational setting and teaching process. Experiences from the user involvement formed the basis for the further development of gLiFE and were discussed in the interdisciplinary team.

One home visit in addition to the group sessions was discussed as an added value to foster efficient implementation of the LiFE activities into daily life but then dismissed due to the required additional costs and resources.

Another feature of gLiFE in favour of cost-effectiveness is the decreased trainer-participant-ratio. Other studies provide evidence for the feasibility of two trainers for a group size of up to 12 older adults [23]. However, less trainer support also poses a potential lack of safety for fall-prone older adults. Therefore, special focus was given to standardised safety guidelines for gLiFE practice. Using chairs and room walls for an additional base of support proved feasible in our study; special and costly equipment such as parallel bars turned out unnecessary. Two trainers were sufficient for delivering gLiFE safely.

Next to reducing costs, we aimed to boost gLiFE's effectiveness. The application of established theories on group learning helped to compensate for the fact that a simple blueprint of the LiFE is not feasible for the group setting. However, the group setting offers several opportunities such as role modelling [27] or social support which are not present in a one-to-one scenario. In gLiFE, we explicitly made use of group dynamics through implementing group discussions and partner exercises in order to foster the learning process.

Moreover, we used special materials and teaching techniques to ensure the transferability of the LiFE activities from the group setting into participants' daily lives. For instance, a poster displaying a kitchen shelf allowed to practice LiFE with relation to common furniture and the respective daily situation (e.g., pick something from a shelf). We know that these features seem quite simple and may not solely facilitate successful transfer, which is why we intensified the already existing teaching techniques such as visualisation and intensively discussed possible daily situations with the group.

In summary, during the development process, we made various trade-offs to ensure gLiFE's cost-effectiveness. The interdisciplinary discourse resulted in a gLiFE concept which contains the core elements of LiFE while having the potential for large-scale implementation. Whether this resource-saving format proves to be similarly effective but less costly compared to LiFE is currently evaluated in a large trial [17].

Conceptual gLiFE framework

We optimised the theoretical framework in terms of structure and content in order to increase gLiFE's long-term effectiveness on basis of current scientific evidence. The first pillar *LiFE Activities and Principles* was maintained, whereas the concept of how to introduce the LiFE activities has been revised. Introducing the LiFE activities gradually and repeating the LiFE activities in the subsequent session allows participants to familiarise themselves with the LiFE activities and test them in daily situations between sessions.

The second pillar *Theory of Behaviour Change and Behaviour Change Techniques* shall ensure the sustainable implementation of LiFE. Theories such as the HAPA or the Self-Determination Theory were not only used to design the theoretical units, but also provided a basis for the teaching aim. For example, participants' competence was fostered through teaching the LiFE principles and emphasising the reasoning behind the importance of situational cues to the participants in order to create new movement habits. Using implementation intentions to link the daily situation to one specific LiFE activity, as in the original LiFE programme, seems to be a promising tool to boost habit formation.

In contrast to former studies [20] which did not provide specific information on instructing a group-based LiFE format, our manualised gLiFE concept ensures standardised dissemination in a variety of public health settings and improves replicability in scientific studies. Furthermore, gLiFE entails a comprehensive description of the contents on behaviour change and the BCTs and thereby allows their standardised application. Providing trainers with limited psychological background with prepared information on long-term behaviour change might increase gLiFE's success.

In summary, the new conceptual gLiFE framework not only offers a profound theoretical basis which can be tested in scientific settings, but also provides detailed information on instructing gLiFE which may help to implement gLiFE on a large-scale.

Part II: Feasibility testing

The gLiFE feasibility testing was carried out as planned. Qualitative and quantitative outcomes obtained via multimodal evaluation suggest that gLiFE is feasible and well-accepted in the target group. Findings are in line with previous studies in young female seniors (mean age 66 years) [20]. We demonstrated that the gLiFE concept is also feasible and accepted in an older sample including individuals at risk of falling and functional impairment who display the key target group of LiFE. Our gLiFE concept could be a resource-saving alternative to LiFE feasible for large-scale implementation.

Quantitative feasibility measures

We used established quantitative measures in order to judge the core elements of gLiFE's feasibility. The fact that gLiFE was generally highly accepted by participants is in line with other LiFE studies [16, 21] and suggests that it is well-suited for the needs and capabilities of the target group. The high attendance rates mirror this finding.

Ensuring safety is one fundamental aspect of feasibility. At the same time, effective balance training requires participants to practice close to their stability limits (overload principle [62]) which has risk-potential in a group of fall-prone older adults. Our developed structure to teach LiFE activities in the group (e.g., two trainers and specific organisational settings) may explain participants' feelings of safety expressed during the evaluation. The assumption of gLiFE being safe is supported by the fact that no adverse events occurred during group sessions. Likewise, participants did not report any adverse events while practicing the LiFE activities in everyday life, suggesting that participants understood the recommendation for practicing LiFE safely.

The key element of the gLiFE concept are the 14 LiFE activities of which participants may include as many as they like. In the case of lifestyle-integrated training, the number of LiFE activities implemented is both an adherence measure and a marker for behaviour, because the main aim is that participants practice at home independently. The fact that most participants implemented around 75% of LiFE activities is in line with their reported low difficulty of implementing LiFE activities into daily situations. Our finding is comparable to adherence rates from previous studies (76%) implementing LiFE after a one-to-one delivery [19] and measuring adherence in the same manner. This implies that gLiFE facilitates the transfer of LiFE activities from the group setting into daily life. Likewise, the frequency of practicing LiFE—which is highly dependent on the daily situations the activity is liked to—is comparable to previous LiFE studies [12]. This suggests that brainstorming daily situations together via group discussions might be as useful as doing it one-to-one.

In summary, quantitative data suggests that the developed gLiFE concept may be as feasible as LiFE. A direct comparison between LiFE and gLiFE in future studies will clarify if one format is more or less effective.

Qualitative feasibility measures

Participants' positive feedback about the group setting and atmosphere in the focus group suggest that a peer group might be beneficial for evoking feelings of comfort, joy, and motivation [63–65]. The perceived high safety level during sessions is in line with previous studies [23].

The positive feedback about structure, content, and distribution suggests that the gLiFE concept is suitable for the target group. The reported high degree of autonomy when choosing and implementing individual LiFE activities suggests that the gLiFE concept empowered participants to manage their LiFE training independently.

The perceived helpfulness of action planning and identification of situational cues indicates that participants understood these two features to be crucial for habit formation and long-term success with LiFE. The fact that some LiFE activities already became habitual after the intervention phase of 7 weeks supports that raising the importance of habit formation in the theoretical basis (pillar II) is a promising approach for promoting long-term behaviour change. However, some participants reported to perform the LiFE activities independent of their chosen specific daily situation. This might hamper habit formation because repeating the action in the same context is considered essential [35, 66, 67].

The decrease in overall pain and the increase in general feelings of fitness and self-efficacy after

gLiFE suggest that gLiFE may not only have an impact on functional status but might also be beneficial regarding overall well-being. These findings are in line with previous studies [16, 21, 65], especially the effects of LiFE on psychosocial factors display an interesting topic for further research.

Exploratory self-reported measures on behaviour change

The fact that the intention stayed high over the course of the intervention suggests that participants kept their aim of being active until after intervention. However, a large gap between the intention to engage in physical activity and real physical activity behaviour has been observed [68], which is why intention should not be considered the only predictor for physical activity behaviour. Studies found evidence for self-regulatory strategies being capable of bridging this "intention-behaviour gap" in the physical activity domain [69].

The descriptive increase of self-determined motivation may support the assumption that gLiFE fosters autonomy and thereby fosters self-determined motivation [38] which could contribute to long-term maintenance of the LiFE activities.

The descriptive increase of action planning suggests that participants made use of implementation intentions in order to plan when and where they would implement the LiFE activities into their daily routines. Even though no conclusions can be drawn on these descriptive findings, they can be interpreted as an initial indicator for a successful application of implementation intentions. Other studies did not evaluate the use of implementation intentions particularly, but found planning interventions to be highly useful for the LiFE context [16, 20] as well as for the formation of physical activity habits [70, 71].

The descriptive increase of habit strength after 7 weeks of practice suggests that habit formation was successful in this small sample. This finding is in line with another group-based LiFE pilot study [20] and other studies investigating habit formation in the health behaviour context [34].

Limitations

In line with the MRC guidelines, this initial feasibility study demonstrates the proof-of-concept of the newly developed gLiFE concept. Large-scale implementability and cost-effectiveness could not be evaluated yet, but a large study building on the present one is currently being carried out [17].

A core element for intervention implementation is fidelity [72]. In this pilot study, trainers reported that intervention implementation was successful, but we did not systematically assess fidelity based on a specific methodology, as this would have required additional resources [21, 22], which were not available in the LiFE-is-LiFE project [17]. Fidelity is certainly a key aspect in larger studies evaluating the gLiFE concept.

The small and selected sample hampers a generalisation of findings. Even though a researcher unknown by participants conducted the focus group, a potential report bias cannot be excluded, as our participants were specifically interested in research project participation. Further, social desirability [73] might have biassed participants' critical feedback on gLiFE. One-to-one interviews could have revealed more specific information on participants' opinions.

Despite our effort to simplify the activity planner, some participants still found it complex to handle. This may display a general limitation of paper-pencil-based materials related to LiFE. An ICT-based solution could be a promising alternative [18]. Further, the question remains whether the documentation critique is truly related to the paperwork or a general issue related to behaviour change (i.e., action control).

Future research

After the development (part I) and initial feasibility testing (part II), the next step is evaluating gLiFE's cost-effectiveness and large-scale implementability. In the currently running LiFE-is-LiFE trial, we evaluate these aspects including quantitative and qualitative outcomes on participants' experiences with gLiFE (e.g., group size, organisational setting, and materials), adherence to LiFE post intervention and behaviour change outcomes such as self-determined motivation and habit formation [17].

Conclusion

This concept paper presents the development (part I) and initial feasibility testing (part II) of a novel gLiFE concept for community-dwelling older adults at risk of falling. According to the MRC framework, these first two steps are crucial for achieving high quality of complex interventions. The greatest innovation of our study is the first standardised version of a group LiFE concept, including a manual on its conduct. gLiFE is based on a theoretical framework and was specifically designed for large-scale implementation. The successfully completed MRC-based development process in combination with the positive results of the feasibility study demonstrates the proof-of-concept of our approach and justifies proceeding to MRC part III (evaluating gLiFE's effectiveness). If gLiFE proves itself as effective as or nearly as effective as LiFE, a wide-spread dissemination of gLiFE into public health settings can be advised, fostering older adults' long-term adherence to fall prevention.

Appendix 1

Table 5 Content, form of delivery and BCTs of gLiFE ordered by first appearance in sessions

Session	Content	Method	Organisation	Material	BCT
1	Introduction of gLiFE	Frontal teaching, open questions	Circle of chairs	Laminated card showing the LiFE team	Information about health consequences[a] (5.1.)
1, 2	Familiarisation/icebreaker	Group work	Open	Name tags	Social support (unspecified) [c] (3.1.)
1–7	Theory-based behaviour change units	Frontal teaching, group discussion, group work, open questions	Circle of chairs	Laminated cards showing the topic, poster with LiFE principles, flipchart	Problem solving[a] (1.2.), instruction on how to perform the behaviour[c] (4.1.), information about antecedents[b] (4.2.), prompts/cues[b] (7.1.), credible source (9.1.), focus on past success[a] (15.3.)
1–6	LiFE activities	Frontal teaching, demonstration by trainers	Dependent on LiFE activity (see Table 6 in Appendix 2)	Laminated cards	Feedback on behaviour[c] (2.2.), social support (unspecified) [c] (3.1.), information about health consequences[a] (5.1.), demonstration of the behaviour[c] (6.1.), credible source (9.1.), social reward[c] (10.4.)
1–6	Assessment of LiFE activities	Group assessment	Dependent on LiFE activity (see Table 6 in Appendix 2)	LiFE Assessment Tool	Social reward[c] (10.4.), graded tasks (8.7.)
1–7	Visualisation	Frontal teaching, individual work	Circle of chairs		Mental rehearsal of successful performance[a] (15.2.)
2–7	Repetition of LiFE activities	Frontal teaching, demonstration in a group, partner work	Dependent on LiFE activity (see Table 6 in Appendix 2)	Additional material (e.g., towels)	Feedback on behaviour[b,c] (2.2.), behavioural practice/rehearsal[b] (8.1.)
2–7	Positive experiences, greatest challenge in execution of LiFE and problem solving	Group discussion	Circle of chairs, semi-circle of chairs		Problem solving[a] (1.2.), review behaviour goal(s) [a] (1.5.), social support (unspecified) [c] (3.1.), social reward[c] (10.4.), focus on past success[a] (15.3.)
1–7	Action planning	Group discussion, individual work	Circle of chairs, semi-circle of chairs	Flipchart, laminated cards showing LiFE activities, flipchart	Goal setting[a] (behaviour) (1.1.), action planning[a] (1.4.), prompts/cues[b] (7.1.)
1–7	Wrap-up/summary	Frontal teaching, open questions, group discussion	Circle of chairs, semi-circle of chairs		

BCT Behaviour change technique. Behaviour change theory is linked to the different BCTs as the following: [a]*HAPA*, [b]Habit formation theory, [c]Self-Determination Theory

Appendix 2

Table 6 Organisational forms for teaching the 14 LiFE activities in gLiFE

	Circle of chairs	Semi-circle of chairs	Semi-double-circle of chairs	Row (of chairs)
Session 1				
Tandem stand	X	X		
Tandem walk	X			
Sit to stand		X	X	
Squatting		X	X	
Session 2				
Leaning				X
Standing/walking on toes	X			X
Session 3				
Stepping over objects	X			
Standing/walking on heels	X			X
Session 4				
Climbing stairs				X
Session 5				
One-leg stand	X	X		
Tighten muscles	X	X		
Session 6				
Move sideways	X			

Appendix 3

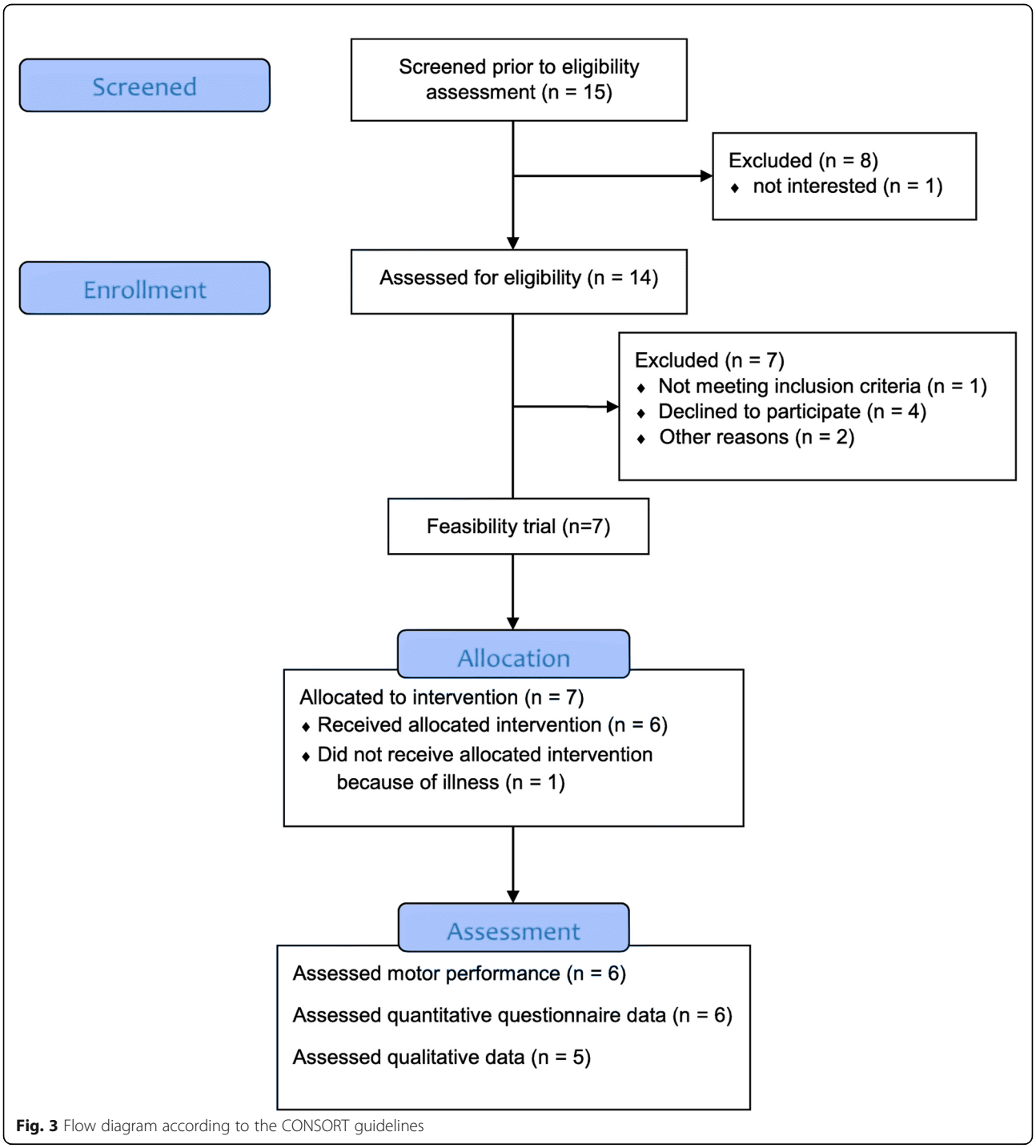

Fig. 3 Flow diagram according to the CONSORT guidelines

Abbreviations

BCTs: Behaviour Change Techniques; BMI: Body mass index; BRE-Q3: Behavioural Regulation in Exercise Questionnaire 3; gLiFE: Group-based Lifestyle-integrated Functional Exercise; HAPA: Health action process approach; IQR: Interquartile range; LiFE: Lifestyle-integrated Functional Exercise; MRC: Medical Research Council; RAI: Relative Automaticity Index

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Authors' contributions

The gLiFE concept was designed by FK, SL, CPJ, CN, LC, and MS with input from all other authors. MS and CB developed the grant proposal for the LiFE-is-LiFE trial approved for funding. FK, SL, and CPJ conducted the feasibility testing leading data collection and analysis. FK and SL produced the first draft of the manuscript. CPJ, CN, LF, LC, and MS critically revised the manuscript for important intellectual content. All authors reviewed, edited, and approved the final version of the manuscript.

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Availability of data and materials

Data of the feasibility study in shape of pseudomised quantitative (data set) and qualitative (texts) are available upon request to interested researchers. Please submit requests to Dr. Michael Schwenk (schwenk@nar.uni-heidelberg.de), Network Aging Research, Heidelberg University, Germany.

Ethics approval and consent to participate

Ethical approval for the feasibility study was obtained from the Ethic Review Board of the Faculty of Behavioral and Cultural Studies at Heidelberg University (no approval number received). All participants provided written informed consent.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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Publisher's Note

Publication III

Leah Reicherzer, Franziska Kramer-Gmeiner, **Sarah Labudek**, Carl-Philipp Jansen, Corinna Nerz, Malin J. Nystrand, Clemens Becker, Lindy Clemson, & Michael Schwenk (2021). Group or individual Lifestyle-Integrated Functional Exercise (LiFE)? A qualitative analysis of acceptability. *BMC Geriatrics, 21*(1), 93. https://doi.org/10.1186/s12877-020-01991-0

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RESEARCH ARTICLE Open Access

Group or individual lifestyle-integrated functional exercise (LiFE)? A qualitative analysis of acceptability

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Abstract

Background: The Lifestyle-integrated Functional Exercise (LiFE) program is an effective but resource-intensive fall prevention program delivered one-to-one in participants' homes. A recently developed group-based LiFE (gLiFE) could enhance large-scale implementability and decrease resource intensity. The aim of this qualitative focus group study is to compare participants' experiences regarding acceptability of gLiFE vs LiFE.

Methods: Programs were delivered in seven group sessions (gLiFE) or seven individual home visits (LiFE) within a multi-center, randomized non-inferiority trial. Four structured focus group discussions (90–100 min duration; one per format and study site) on content, structure, and subjective effects of gLiFE and LiFE were conducted. Qualitative content analysis using the method of inductive category formation by Mayring was applied for data analysis. Coding was managed using NVivo.

Results: In both formats, participants ($N = 30$, 22 women, $n_{gLiFE} = 15$, $n_{LiFE} = 15$, mean age 78.8 ± 6.6 years) were positive about content, structure, and support received by trainers. Participants reflected on advantages of both formats: the social aspects of learning the program in a peer group (gLiFE), and benefits of learning the program at home (LiFE). In gLiFE, some difficulties with the implementation of activities were reported. In both formats, the majority of participants reported positive outcomes and successful implementation of new movement habits.

Conclusion: This is the first study to examine participants' views on and experiences with gLiFE and LiFE, revealing strengths and limitations of both formats that can be used for program refinement. Both formats were highly acceptable to participants, suggesting that gLiFE may have similar potential to be adopted by adults aged 70 years and older compared to LiFE.

Trial registration: ClinicalTrials.gov, NCT03462654. Registered on March 12, 2018.

Keywords: Fall prevention, Focus groups, Qualitative methods, Lifestyle-integrated exercise, Habit formation, Group vs individual exercise, Qualitative content analysis

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Background

The incidence of falls in older persons is expected to increase in upcoming years [1]. Widely disseminated fall prevention programs for community-dwelling, fall-prone older adults aim to impede falls and their individual and socio-economic consequences.

Most evidence-based fall prevention programs are based on 'structured' group exercises conducted at least once a week [2, 3]. These programs often fail to sustain long-term effectiveness due to regressive adherence rates [4].

The alternative approach of lifestyle-integrated training [5] aims for higher adherence rates through long-term behavior change. The Lifestyle-integrated Functional Exercise (LiFE) program [6] embeds functional strength and balance activities into daily life to enhance physical function and activity of adults aged 70 years and older. Implementing activities in recurrent opportunities is used as a strategy to help participants create new habits [7], which constitutes a key mechanism for long-term maintenance of behavior change. LiFE recorded a significant reduction in fall rate (31%) compared to the control group (gentle and flexibility exercises). According to a recent review [8], adherence for LiFE was higher compared to structured training during the intervention periods. One randomized controlled trial rated completing LiFE activities on at least three days a week, or structured home exercises three times a week, as 100% adherence [6]. The results showed significantly higher adherence to LiFE (64% of participants) compared with structured training (53%) [6]. Poor adherence (<25%) was evident in 19% of structured training compared to 7% of LiFE participants [6].

However, its delivery through seven one-to-one home visits requires considerable time and human resources. This has recently been addressed by Kramer and colleagues [9], who developed and tested a potentially resource-saving group-based LiFE (gLiFE) concept, delivered to eight to twelve participants by two trainers in seven group sessions. The authors reported successful implementation and regular execution of activities in daily life: after the last intervention session, participants (n = 6) had implemented 9.5 (IQR = 4.0) out of 14 LiFE activities into their daily lives. Furthermore, five out of six participants had implemented activities five days a week over the course of the program. Effectiveness, however, has not been established yet, as gLiFE is currently being evaluated in an ongoing trial in comparison to the individual LiFE program [10].

Besides evaluating intervention effectiveness, considering participants' attitudes towards such interventions and whether they are acceptable, is essential for long-term success [11]. Acceptability is related to the perceived appropriateness based on anticipated or experienced cognitive and emotional responses to an intervention [12]. The construct of acceptability encompasses different components: affective attitudes, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness, and self-efficacy [12]. Levels of acceptability may critically affect how likely participants are to adhere to home-based exercise, and consequently to benefit from the intervention [13]. Conversely, low acceptance of the intervention can negatively impact its effectiveness [14]. Assessing LiFE's and gLiFE's acceptability is indispensable for intervention refinement, and vital for both research and clinical practice to understand how the intervention formats can be sustainable over time. To date, only a few qualitative studies on this topic exist, although a thorough analysis is recommended in the evaluation of complex intervention by the Medical Research Council guidelines [15]. The main differences between gLiFE and LiFE that may influence participants' acceptance of the intervention are the following:

LiFE participants receive the program directly in their home, facilitating identification and testing of suitable daily situations for implementing LiFE. One-to-one delivery allows a highly personalized training and closer contact between trainer and participants, which could influence participants' exercise behavior and perception of the program. A previous qualitative study on a different LiFE approach [8] for adults age 60 to 70 suggested that trainer support was a strong motivator to carry out the activities. Participants valued the flexibility and personalized nature of the program. In gLiFE, different strategies were implemented to compensate for these missing aspects of individual delivery.

gLiFE participants can potentially benefit from learning the activities in a group. A previous group-based LiFE study [16] suggested that participants valued the support from and interaction within the group. Fellowship and shared experiences with peers have been described as facilitators in maintaining long-term exercise [17]. Social support from an exercise group can enhance motivation [18], affective responses, and the benefits of the intervention [19, 20].

Regarding a potential large-scale dissemination of gLiFE, the current study aims to explore how experiences of participation differ between gLiFE and LiFE, and whether both formats are acceptable to the target population of fall-prone older adults, aged 70 years and older.

Methods

Study design and setting

This qualitative study was conducted with a subsample of participants of the LiFE-is-LiFE trial [10], a multi-center, single-blinded, randomized non-inferiority trial comparing gLiFE with LiFE regarding fall reduction and cost-effectiveness (ClinicalTrials.gov, NCT03462654) (period: 06/2018 to 08/2020). Participants with a verified fall risk

took part in either seven gLiFE or LiFE sessions within eleven weeks, followed by two phone calls. Follow up assessments were performed after six and twelve months.

For the present study, qualitative data collected in four focus group discussions after the six-month follow-up assessments (04/2019) were analyzed.

Programs

LiFE aims to reduce fall-related outcomes and promote long-term physical activity in community-dwelling older adults by integrating balance and strength activities into their daily routines. Program details of gLiFE [9] and LiFE [21] are described elsewhere. Table 1 provides an overview of the similarities and differences between both formats.

Program sessions of both formats were administered by physiotherapists, occupational therapists, and/or sport scientists that had attended a two-day workshop to ensure standardized delivery. Trainers teach the participants how to perform the activities (e.g., squat), where (e.g., in the bedroom), and when to implement these into daily routines (e.g., each time when reaching for the floor drawer). New movement habits are created by linking the LiFE activities to specific daily situations based on behavior change concepts [9, 27].

Participants learn how to adapt chosen activities to their lifestyle and how to increase difficulty to ensure continued progression using LiFE principles [21].

The main difference between programs is the delivery format: group delivery for eight to twelve participants by two trainers (gLiFE) compared to one-to-one delivery in participants' homes (LiFE). In gLiFE, the trainer's role is to teach and facilitate; in LiFE, the trainer teaches and substitutes a training partner. Contents of gLiFE and LiFE are taught in predefined order, but teaching in gLiFE is organized in an interactive manner including group discussions and joint activity practice with peers.

All participants receive the German participant's manual [22] and a workbook, including a modified activity planner [9] and an activity counter to plan and monitor activity performance.

Participants

A total of 310 community-dwelling older adults (> 70 years) were randomized to either gLiFE or LiFE at

Table 1 Similarities and differences between LiFE and gLiFE conducted in the LiFE-is-LiFE trial [10]

	LiFE	gLiFE
Brief aim	Improve balance and lower limb strength, increase physical activity, decrease risk of falling, long-term sustainability of the LiFE activities through habit formation and self-empowerment	
What: Materials	Participant's manual, German version [22]; Contains descriptions and instructions of LiFE activities; principles of balance and strength training as well as physical activity enhancement; safety instructions when performing the activities; background on balance and strength exercise; assistance and support for changing habits and performing LiFE activities Trainer's manual, German version; one for LiFE, one for gLiFE. Contains all information also included in the participant's manual; additionally: outline of all 7 sessions and 2 phone calls, including text templates, material, preparations, and precautions Workbook; for all participants; used during intervention: Includes information on study procedures, personnel, contacts, and safety instructions; activity planning sheets for balance, strength, and physical activity; activity counter, notes pages; LiFE principles Aids and materials during intervention sessions: Laminated cards, showing LiFE principles and LiFE activities to be used as visual aids during intervention sessions; balls, blankets, sponge rubber, boxes, clipboards, pens, bags, name tags, flipcharts	
What: Procedures	7 home visits by one qualified trainer; 2 phone calls 4 and 10 weeks after last session	7 group sessions (n = 8–12 participants) led by one main and one co-trainer, 2 phone calls 4 and 10 weeks after last session
Who provided	Trainers are sport scientists, physiotherapists, occupational therapists or psychologists. All trainers received a two-day training course on the program background, aims, and components prior to the project start.	
How	One-to-one situation in the participant's home	Group setting with 8–12 participants and two trainers
Where	Two study sites: Heidelberg and Stuttgart (Germany)	
When and how much	7 sessions within 11 weeks: week 1, 2, 3, 5, 7, 9, 11. Two phone calls 4 and 10 weeks after the last session (i.e. week 15 and 21). Duration of each session: 1–1.5 h	See LiFE Duration of each session: 2–2.5 h
Setting	Intensity and dose are determined by the individuals' activity plans, adherence, and performance level of each activity	
Behavior change	Behavior change theories based on LiFE trainer's manual and participant's manual [21].	Modification of the original behavior change concept using established theories on health behavior, such as the Health Action Process Approach [23, 24] and the Self-Determination Theory [25]. Intervention contents of gLiFE were mapped using the Behavior Change Technique (BCT) Taxonomy v1 [26].

two study centers in Germany (Network Aging Research, Heidelberg University; Robert-Bosch-Hospital, Stuttgart). For this study, 30 participants (22 women, 8 men; M_{age} = 78.8; range 70–96 years; n_{gLiFE} = 15; n_{LiFE} = 15) were purposively selected [28] from the trial. We ensured to include participants who reported higher and lower levels of habitualization of the LiFE activities at the six-month follow-up. Habitualization was indicated by the Self-Report Behavioural Automaticity Index (SRBAI) [29]. The SRBAI median split [30] was defined as the threshold (SRBAI ≥4.49 = higher behavioral automaticity, SRBAI ≤4.49 = lower behavioral automaticity). We composed each focus group of participants with different ages, gender, and different SRBAI scores to maximize the breadth of information and foster discussion between participants that did and did not successfully implement LiFE. To determine whether the sample size of our study and the number of focus groups conducted was sufficient, we followed the systematic model of information power in qualitative study [31]. It states that a study will need a smaller number of participants if the study aim is narrow, if the combination of participants is very specific for the study aim, and if the study is supported by established theory. Taking into consideration that these aspects are fulfilled in this study, in combination with empirical evidence by Guest et al. [32] identifying that 90% of all themes found in a focus group analysis were discoverable within 3 to 6 groups, we determined that the number of focus groups and participants is sufficient to provide the information we sought.

Participant characteristics are summarized in Table 2; they were predominantly female (73%), educated, at risk of falling indicated by the Timed Up and Go Test [34], and were cognitively healthy according to the Montreal Cognitive Assessment (MoCA) [33]. On average, participants had two co-morbidities and took five medications per day. Participants were invited via telephone. The recruitment process is shown in Fig. 1.

Data collection

An interdisciplinary team of exercise scientists, psychologists, and physiotherapists developed a semi-structured interview guide (see Additional file 1) for both formats based on a previous LiFE focus group discussion [9].

The interview guide comprised 14 main questions on the programs and their components, the group and individual format, and habit formation processes like action planning or building new movement habits. It was piloted with one LiFE-is-LiFE participant regarding clarity of questions and refined after pilot evaluation.

Two focus group discussions were conducted at seminar rooms in each study center, one for gLiFE ($n_{Stuttgart}$ = 8, $n_{Heidelberg}$ = 7), one for LiFE ($n_{Stuttgart}$ = 7, $n_{Heidelberg}$ = 8) lasting between 90 and 100 min. At the beginning, the study purpose (evaluation of program acceptability) was explained, and participants gave written informed consent. The moderator facilitated discussions by

Table 2 Characteristics of participants (*N* = 30)

	Mean (SD) or % (n)		
	Total (*N* = 30)	**gLiFE (*N* = 15)**	**LiFE (*N* = 15)**
Age, years	78.8 (6.6)	78.5 (6.1)	79.1 (7.2)
Women	73.3 (22)	73.3 (11)	73.3 (11)
MoCA, score (0–30)	26.0 (1.7)	26.5 (1.8)	25.4 (1.5)
Fall incidents at baseline	30 (9)	20 (3)	40 (6)
Completed years of education	14.1 (3.8)	14.5 (4.5)	13.7 (3.0)
Highest school degree			
Secondary school	43.4 (13)	46.7 (7)	40 (6)
Advanced college certificate	3.3 (1)	–	6.7 (1)
General university entrance qualification	50 (15)	46.6 (7)	53.3 (8)
No degree	3.3 (1)	6.7 (1)	–
TUG, sec.	12.7 (3.4)	12.7 (2.7)	12.7 (4.0)
BMI	27.3 (4.6)	26.6 (4.5)	28 (4.7)
Co-morbidities, number (0–6)	2.3 (1.5)	2.5 (1.6)	2.2 (1.4)
Medications, number (0–21)	5.2 (4.2)	5.4 (4.6)	5.1 (3.8)

Note. *MoCA* Montral Cognitive Assessment [33], *Fall incidents* Falls in the last 6 months at baseline measurement, *TUG* Timed Up and Go Test [34], *BMI* Body Mass Index

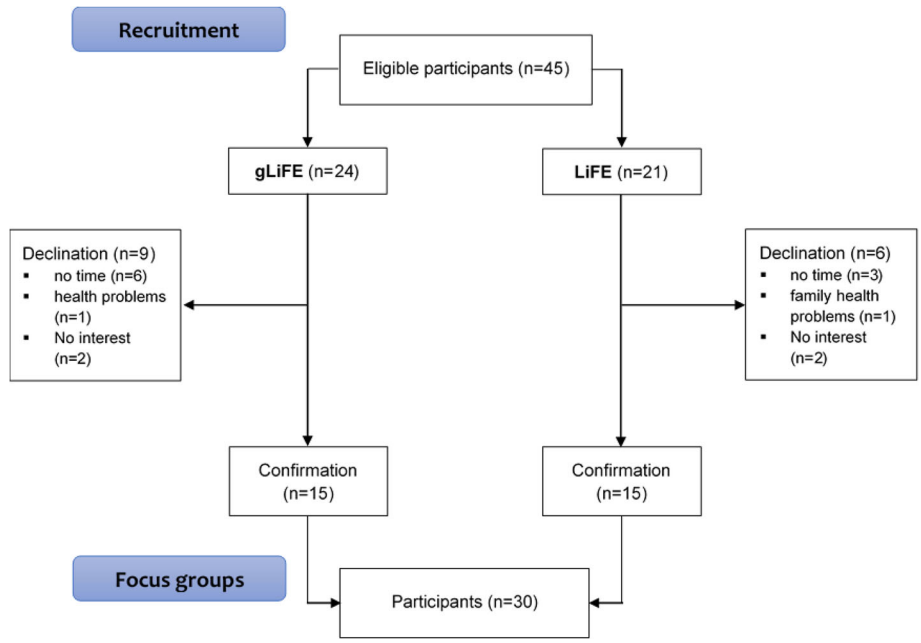

Fig. 1 Recruitment process

asking questions with follow-up prompts, probing, encouraging reserved participants to speak, and ensuring that discussions covered the main topics. The moderator (main author, physiotherapist, and external researcher) and co-moderators (team members) were not involved in follow-up assessments and intervention delivery. Co-moderators took notes and kept time. Two of the co-moderators who took part in the program development stayed silent during discussions. Focus groups were audio recorded and transcribed verbatim in German, according to transcription guidelines by Kuckartz [35].

Data analysis

We performed a qualitative content analysis according to Mayring [36], following the procedure of inductive category formation. Coding was managed using NVivo 12 (QRS International, Australia). Categories were not predetermined but instead defined by the researchers as near as possible to the material [36]. The step of paraphrasing all text can be skipped and only the material relevant for a specific research question has to be considered. For this selection process, we formulated a selection criterion including the definition and components of acceptability [12] and more general evaluations of the programs. This approach was chosen to be open to themes emerging from participants' statements that may not directly relate to acceptability (e.g. on habit formation), but are nevertheless important to understand how to refine the program.

All focus group discussions were defined as the unit of analysis and the manifest content was analyzed. The selection criterion (expression of affective attitudes towards the programs, burden, coherence, perceived effectiveness and self-efficacy, and general evaluations of program components of the LiFE or gLiFE program) was used to determine the relevant material from the text. In addition, a level of abstraction was determined, which defines how general or specific categories should be formulated [36]. Based on this, text was coded line-by-line and either a category was constructed and named every time an element of the text fulfilled the selection criterion (see Table 3), or the text was subsumed under an existing category. After 50% of the text, categories and coding rules were revised, then two authors (LR, FKG) independently coded the text. Main categories were formulated and discussed. In case of a disagreement, a third researcher (SL) was consulted. Finally, categories were organized into overarching themes and contents were

Table 3 Example of inductive category formation

Coding unit	Keywords	Category	Main category
"I would have liked to go to a group. I found the individual home visits, it was a bit too less. And a group is more intense".	Group is more intense	Motivation because of group	Format of the program
"No, the group pressure is necessary. For me at least. […] Always just my own enthusiasm, it is limited".	Group pressure is helpful		

contrasted by group (gLiFE vs LiFE). The organization and naming of overarching themes was shaped by the main topics of the interview guide. Three authors (LR, FKG, SL) agreed on the final category framework.

Results

Five overarching themes were identified: Program overall, trainer support, content of the program, format of the program, and changing behavior. The results are illustrated by quotes, translated from German to English. Participants are identified by group, gender, and age (e.g., gF73 = gLiFE, female, 73 years; oM80 = original LiFE, male, 80 years).

Program overall

Participants reaction to the overall program did not differ much in the two program formats. In both formats, participants were positive about the program: *"The LiFE-program is great and I enjoyed it"* (gF73*); "It seemed […] very well structured"* (oM78). Most participants understood and liked the concept of lifestyle-integrated exercise: *"And what I found appealing is that these are exercises that can be integrated into daily life"* (gF70). Many participants further valued the focus on independent exercising: "*Doing my own thing at home alone, not having to join any sports clubs or groups, that is exactly the right thing for me"* (oM80).

Participants experienced some troubles with the paperwork for the study. The monthly fall calendar and the set of questions at baseline and follow-up assessments were perceived as "*quite annoying" (*gF70) by some participants in both formats.

Trainer support

In general, gLiFE and LiFE participants spoke positively about the teaching styles of their trainers: *"The guidance and instructions were great […] and well explained"* (gM82) and "*I think, my impression was entirely positive. He [the trainer] had a very good pedagogical approach. So, it was very clear*" (oM80).

Participants in both formats felt individually supported by the trainers during teaching sessions. LiFE participants described how the trainers adapted the programs to their abilities and gave feedback on their performance during activities: *"She really catered to my needs and abilities and had another idea, on how to adapt things if I could not do them" (oF72).* gLiFE participants described how the trainers approached them individually within the group setting. *"They really responded to the individual's situation" (gF77); "They would correct the execution of activities in a very caring way, I would say. So, when someone did not do it correctly, then they very gently approached you and said, try this or try that." (gF70).*

For gLiFE participants, it seemed important not to feel pressured by trainers or exposed in front of their peers when they were having difficulties with an exercise: *"You never had to feel embarrassed. For example, I have a problem with my hip and I cannot step over objects sideways. But nobody gave me a weird look and I could just tell the trainers that I cannot do it […] and never felt pressured"* (gF72).

LiFE focus groups discussed their relationship with the trainers in more detail, for example by praising their personality (e.g. how cheerful or friendly they were): *"He [the trainer] always arrived with a big smile on his face and we were always happy to see each other. He was always so cheerful, even in the morning"* (oF80). Furthermore, they described the one-on-one supervision as an opportunity for a personal exchange with the trainer: *"So I liked that you could talk to them about personal stuff, too. There was an exchange and I really enjoyed that. We had great conversations"* (oF74).

Content of the program

Structure and materials Participants from both formats liked the *"whole structure"* (gF84) of sessions and the *"well balanced and instructive*" (gM82) combination of theory and practice. One gLiFE participant specified that the repetition of activities from the last sessions was helpful: *"It really gets stuck in your mind; you don't hear it just once and then you have to be able to do it and then there's a different program next time, but instead it was repeated before adding something new*" (gF80).

In both formats, participants valued the manual as a helpful tool "*especially at the time when the trainer is not there anymore"* (oM74).

Activities gLiFE and LiFE participants indicated strong preferences for activities that are easy to integrate into daily routines, like the one-leg stand: *"I think the most beneficial are the activities, that can be successfully implemented in everyday tasks" (*oM80). Participants of both formats talked about activities which were difficult to perform or which they perceived as *"not natural"* (gF73) or *"silly"* (oM80), like "*stepping over objects backwards"* (gF91). They often related difficulties with certain activities to personal health conditions or pain:"*For me it is difficult, because my knees cause a lot of troubles. I cannot do many of the activities"* (oF96).

gLiFE participants reported that they consider safety aspects when practicing at home: *"I always make sure, when practicing […], that I am close to the wall"* (gF82). LiFE participants did not make specific statements on safety.

Only gLiFE participants suggested to add more activities, like "*some kind of coordination"* (gF84) or to practice

more complex movements like *"getting out of a bathtub"* (gF82). One LiFE participant wished for more specific fall prevention exercises to learn *"how to fall and how to compensate a fall" (oF73).*

Intensity and duration Participants had different opinions on program intensity, with most being satisfied. Few expressed that the intensity *"was slightly too little"* (oF80) compared to similar exercise programs. Some participants wished for more practice time during sessions, as well as increased difficulty or more challenging exercises: "*Strength could be a little bit more [challenging], to guarantee stability"* (oM83).

Format of the program

Group format When asked about their thoughts on the other format, gLiFE and LiFE participants addressed advantages of group exercising. gLiFE participants reported that the group enhanced their motivation: "[…] *it wakes your ambition. You do not want to step down, you want to keep up with the others"* (gF88). A good atmosphere in their groups motivated and encouraged them: "[…] *in the group it is, I think, a bit funny from time to time. You encourage each other"* (gF88). Not all gLiFE participants had the same experience of group cohesion in their groups and had wished for more group interaction: *"So, to be honest, I never felt a sense of companionship, unfortunately. (…) I would have liked to experience some team spirit, to have an exchange"* (gF84).

Several gLiFE participants described the exchange and comparison with peers as "*comforting*" (gF91) because they "*all face difficulties with walking and climbing stairs, and they are all troubled by their knee pain"* (gF91).

LiFE focus groups discussed "group pressure" and peer exchange as positive effects of exercise groups, based on previous experiences or preconceptions: "*The group pressure, […] yields more than fumbling around alone with the trainer"* (oM74). Some said they would have preferred "*being part of a group of like-minded people"* (oF96) for the social aspects, and to have an exchange with peers because *"you always have this one person [the trainer], who you of course can always have an exchange with, and who gives good advice, but in everyday life it's different. We're all older people and you [research team] can't really understand how we feel" (oF82).*

Individual format LiFE participants agreed that it was helpful to receive individual support to identify situations and locations suitable for the implementation of activities directly in one's home: *"The advantage of him [trainer] being in my home was that we could choose situations together in which it [activity] can be implemented"* (oM80). LiFE participants appreciated the flexibility of home visits (e.g. individual scheduling, no travel time) and the individual supervision by a trainer: "*That's why I was really glad to have my own trainer. Who could tell me, that I was doing it correctly. Who corrected me"* (oF80).

gLiFE participants suggested that receiving one home visit in addition to the group sessions, *"to have one's attention directly drawn to where in the house, when in the household, you could do this",* would be *"an enhancement"* (gF84).

In LiFE, the transition from being supervised by a trainer at home to practicing alone might have been more difficult; one LiFE participant recalled the two booster phone calls as important: "*First you have the regular supervision and suddenly it stops. And then you have to see how to get on alone. And I found it [phone call] quite good"* (oF72).

Changing behavior

Forming habits Participants from all focus groups identified opportunities to integrate activities into daily routines, and some activities became habitual: "*For me, it became a habit – I don't want to say that I do everything. But now I tend to remember it and then I do it" (gF82)* and *"[…] it's like learning a new language. In the beginning you're studying two, three hours every day and then at one point you know the basics and can just use them without thinking"* (oM78). gLiFE and LiFE participants described activities being connected to situational, object-related, or activity-based cues: *"It did indeed remind me, when in a certain course of action, AHA!, now you could integrate this"* (gF84).

Planning actions One key psychological strategy of both interventions is action planning. One gLiFE participant described that the activity planning helped her: "*It [activity planner] was really good to get started […] because it provides an incentive […] to actually do it*" (gF70). However, a few gLiFE participants felt like the action plans they made during the group sessions were not applicable in a home environment: "*How I was doing it in the beginning, doing this and that while brushing teeth, that just did not work" (gF78).* Some LiFE participants found the activity planner tedious and *"too silly*" (oM80). One LiFE participant specifically stated*: "I would like to do it spontaneously […] I could never say, so now when I brush my teeth I do this forward and backward thing, only when it comes to my mind I do it"* (oF82).

Outcome experiences The majority of gLiFE and LiFE participants shared positive outcome experiences, like

improvements in physical function or mobility ("*Since I walk the stairs so often, […] my knee became better*", gF70) or a more active daily life ("*I use the car less often*", oF74). A few participants reported improvements in their fear of falling: "*For me it took away the fear of falling" (*oF92). Others stated that their fear of falling was persistent: *"Despite participating in this program, I am always afraid of falling again"* (gF78).

Confidence in doing gLiFE and LiFE participants were confident about their capability of performing the activities and saw practicing LiFE as their own responsibility: "*If I don't have the discipline myself, then another session is not going to help me […]*" (oF72). A few participants in gLiFE reported adopting a role as a motivator for others to be more physically active: "*So you can teach others, if you want to of course and if they accept it. You can motivate them and say, simply integrate this into your daily life. And that does, it does really help"* (oF82). Some LiFE participants anticipated that their exercise routine might fade without regular home visits over time. One of the LiFE focus group participant stated that not seeing the personal relevance for themselves, or more important things on their agenda, kept them from implementing activities into their lives: *"As I have already said, I don't take this [LiFE] so seriously. I have a lot of other things to do in my life, I have a house, I have a garden to take care of and then I also have a lot of hobbies* (oF80)". Both LiFE participants and gLiFE participants describe their confidence being influenced by what others might think about them exercising: "*I live on the ground floor and many people pass by outside and if I for example walk on my heels I watch and make sure that nobody thinks, 'oh god, what is she doing, how is she walking around so stupidly.' It looks so foolish"* (oF74).

Discussion

This is the first qualitative study comparing and describing participants' experiences of gLiFE and LiFE, to identify whether both programs are acceptable to community-dwelling older adults at risk of falling. The programs' acceptability to the participants will be analyzed using a selection of Sekhon's [12] component constructs for acceptability, namely: intervention coherence, affective attitudes, burden, perceived effectiveness, and self-efficacy.

Participants found both LiFE programs acceptable, indicating that both formats are suitable for the target group. LiFE's main aim, integrating the activities into daily life, was well received and understood by gLiFE and LiFE participants. This perception of so-called intervention coherence (the extent to which participants understand the goal of an intervention and the mechanism behind it) positively influences acceptability [12]. The possibility to train independently in one's home was perceived as a strength of both LiFE formats. These results underline findings from previous LiFE feasibility studies delivered one-to-one [6, 8] or in a group [9, 16, 37], further supporting that LiFE can be seen as a promising alternative to structured fall prevention programs [5], also in a group setting.

In both formats, the support by trainers played an important role for the participants' affective attitudes towards the program. Previous studies highlighted that professional help and the motivational support of an exercise specialist were important factors in older adults' attitudes towards, and attendance of, exercise classes [38]. The perception of being addressed individually by trainers, in both LiFE and gLiFE, indicates that gLiFE also offers opportunities for individual support. Our findings are in line with a previous study of LiFE showing that individual content adaptation is indispensable to enhance acceptability and exercise adherence [39]. Only LiFE participants addressed their trainer's personality traits, suggesting that individual training and personal exchange strengthen the trainer-participant relationship in LiFE compared to gLiFE. gLiFE participants appreciated that they never felt pressured by trainers when they had difficulties performing some LiFE activities during group sessions. This is in line with research showing that a trainer's controlling coaching style can decrease a participant's autonomous motivation [40]. Trainers that reaffirm participants in their own decision-making and respect their individual capabilities are an important factor for building motivation and confidence in gLiFE. The perception of self-efficacy, i.e. the participants confidence to perform a required behavior, was found to be crucial for the acceptability of an intervention [12]. In gLiFE and LiFE, the majority of participants said they were confident in being able to perform the activities and to maintain the exercise routine. Our findings suggest that both formats were able to support participants in building the confidence to sustainably engage in LiFE.

The structures of gLiFE and LiFE were well received, particularly the repetition of learned activities at the beginning of each group session were perceived as helpful to remember and to consolidate the movement execution. This indicates that the structural modifications developed for gLiFE [9] were appropriate. As in previous LiFE studies [9, 41] participants perceived the LiFE manual as a helpful tool for corrections which highlights usefulness of a manual in both groups.

In both formats, participants preferred activities that were easy to integrate in daily life. The importance of activities being achievable and easy to integrate into daily life routines has been discussed before [41]. Specific LiFE activities were perceived as too artificial or difficult to perform, e.g. due to personal health problems. This finding

has already been described by Boulton et al. [8]. Therefore, assessing which and why certain activities are not feasible, as well as increasing participants' autonomy might be essential. Indeed, previous qualitative evaluations of LiFE showed that integrating participants' ideas may be important to facilitate their long-term goal achievement [8].

gLiFE participants stated that they took care of their safety while practicing LiFE at home, so gLiFE seems to sufficiently convey important safety aspects of home exercise. We can only speculate why LiFE participants did not discuss safety aspects: maybe these were considered less important or handled more naturally without participants actively reflecting on them as they learn and practice LiFE directly in their home setting. Fear of falling, and improvements in fear of falling, were mainly addressed by LiFE participants. Addressing the fear of falling was not in the scope of the programs, and this focus of participants could be explained by their previous experiences: LiFE participants in our sample reported a higher number of fall incidents at baseline compared to gLiFE participants.

The burden of participation is a relevant component construct of acceptability [12]. The required paperwork for the study (e.g. monthly fall calendar) was perceived as time-consuming by both gLiFE and LiFE participants. Even though documentation mainly related to the study and will be much shorter in a potential roll-out of the programs, it may have influenced acceptability of programs. Overall, participants statements indicate satisfaction with gLiFE's and LiFE's intensity, suggesting that the perceived effort to participate in the program (i.e. physical and cognitive requirements) was generally appropriate. A few participants of both formats felt they were not challenged enough by the activities after some time. The principle of upgrading the difficulty of the activities might have been insufficiently conveyed by the trainers, therefore the participants may not have fully understood that they should adapt activity intensity. On the other hand, it could be that participants preferred to practice in their "comfort zone", instead of putting themselves into unstable or exhaustive situations to challenge themselves. Revising the theory class on upgrading exercise should be considered for future studies to ensure the participants' awareness of the importance of gradual intensity progression [42]. The nature of lifestyle-integrated exercise (small activity bouts throughout the day) might feel less challenging compared to exercising for a set period of time.

Participants of both formats named various benefits when asked about their thoughts on learning LiFE in groups (e.g. being more motivated due to social comparison or social support), which is in line with studies that emphasize the importance of peer contact in fostering positive physical activity experiences among older adults [43, 44]. Studies demonstrate that when people do exercise in groups, especially when participants experience cohesion, adherence levels [19] or outcomes like functional balance [45] improve significantly compared to exercising alone. As argued in the Self-Determination Theory [25], social contextual events like peer feedback can foster feelings of competence and enhance intrinsic motivation. Low motivation has been identified as a cause for adults not to adhere to home-based activities [18]. Based on our findings, the social aspects of the group as a motivating factor could be considered an advantage of gLiFE over LiFE. Nonetheless, not all gLiFE participants experienced group cohesiveness. Previous studies showed that task and social cohesion (individual attraction towards the group task and the group members) are related to older adults' exercise adherence [46]. We suggest that the facilitation of group processes in gLiFE should be refined to foster group cohesion. Increasing the feeling of being understood by the trainers could be achieved by employing trainers which are nearly the same age as participants. This has been found effective in other settings like diabetes care [47].

LiFE participants were satisfied about receiving individual training at home. This supports previous research [48] pointing at the preference of older adults' for home-based activities and/or exercising alone, and highlights the importance of individual preferences for exercise settings. gLiFE could be a good compromise as it combines group-based teaching with independent home-based training.

A single home visit to support implementation of activities was suggested as a possible improvement to gLiFE by participants. Adding one single home visit to gLiFE would reduce its' assumed low-cost delivery, and hence financial feasibility and large-scale implementability from a stakeholder perspective. Although some gLiFE participants had difficulties finding the right daily cue during group sessions, results suggest that the principle of tying LiFE activities to different situational cues in order to create new movement habits was understood by most participants. This supports study findings of group-based [16] and individual LiFE [8]. The fact that not being in the home environment could cause difficulties in action planning was addressed in the design of gLiFE by including compensational strategies, like group discussions to collect the participants' suggestions for possible situations to implement activities [9]. Not only in gLiFE did difficulties in action planning occur, as LiFE participants also perceived action planning and habit formation as challenging. In the future, more guidance and direct suggestions from trainers should be offered for action planning if needed.

Participants from both LiFE formats spoke about perceiving positive program effects, like more activity in daily life, and improvements in mobility and function. Perceived effectiveness has been described as one relevant property of acceptability [12]. Positive outcome experiences were found to increase satisfaction, which increased the likelihood of a sustained exercise routine [49].

To summarize, we describe the important differences between both intervention formats: in gLiFE, the social aspects of learning the program in a peer group seem to positively influence participants' affective attitudes towards and motivation to participate in the intervention. Indeed, some LiFE participants wished to take part in the group to benefit from social interactions and new peer contacts after the program ended. On the other side, LiFE participants appreciated the one-to-one training and valued the individual training as an advantage for implementing the LiFE activities into daily routines. In gLiFE, the implementation of activities into daily routines was perceived as more difficult compared to LiFE. Regarding acceptability, individual training may decrease the burden placed on participants: less travelling is needed, sessions can be scheduled flexibly, and the supervision is individual.

Our analysis identified several similarities between both intervention formats: Participants reported a positive overall attitude towards the programs, and specific program features like the selection of activities. The majority perceived the program as having effects on their daily life activity or movement habits and were confident in their ability to keep practicing LiFE (self-efficacy). Overall, this focus group study indicated that both LiFE formats were acceptable to the participants.

Strengths and limitations

Qualitative methods play a valuable role in exploring participants' experiences of study participation. Their use is increasingly recognized as the best practice in the development [15] and evaluation [50] of complex interventions. The conceptual definition of acceptability used in this study offers a clear guidance on what experienced acceptability is and what its components are. Without a strong theory base, acceptability is easily confounded with satisfaction [12], thus relying on a framework ensures capturing key dimensions of acceptability. The study sample represents the target group of the original LiFE program [6], is based on clear inclusion criteria from the LiFE-is-LiFE trial (Jansen et al., 2018), and captured varying experiences with the program.

Some limitations need be addressed. A larger proportion of women (70%) compared to men were included in our sample. However, this reflects both the population of the trial, with a higher participation rate of women (73.5%), and the general population in older age groups (> 80 years old) with a predominant female demographic [51]. Education level was higher in the focus group sample (53% of participants with German university entrance qualification) compared to the trial (35.7%), as this was not a sampling criterion. We acknowledge that the experiences might have been different for older adults of other background or gender, which could be the focus of future research. Our purposive sampling strategy allowed us to study the groups of older adults most likely to enroll in fall prevention programs like gLiFE or LiFE.

Although free conversation about topics that were relevant to participants was encouraged, the discussion of life experiences or circumstances outside the program that may have influenced the individual's attitudes towards the programs may have fallen short. As participants lived in the same areas, we could not avoid that some of them were familiar with each other. Overall, participants reported more positive elements about both interventions than negatives. Social desirability, defined as a tendency to reflect reality in a sense that it is consistent with what is perceived as being socially acceptable [52], is a common problem in qualitative research. During focus group discussions, participants were frequently reminded that all answers are acceptable and open discussion was facilitated. Nevertheless, social desirability could have prompted positive rather than negative answers or created a consensus in the group about exercise behavior or opinions on the program [53].

Conclusion and implications

This is the first study to explore participants' views on and experiences with gLiFE and LiFE, which are essential factors for the programs' long-term success [11]. Assessing acceptability yields important information for program development and evaluation and should therefore more often be a component of intervention evaluation. The identified strengths and limitations of both programs from the participants' perspective could be helpful for program refinement and complement quantitative findings in later stages of the program evaluation. Future studies should focus on possible solutions to the identified limitations, for example the revision of the strategies used in gLiFE to help participants find situations for the implementation of LiFE activities.

In summary, our study showed that fall prone older adults perceived participation in gLiFE and LiFE as beneficial and that both formats were well accepted. Hence, gLiFE and LiFE could be appropriate for

implementation within public health initiatives. Whether gLiFE has non-inferior or superior effectiveness compared to LiFE is currently examined [10].

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12877-020-01991-0.

Additional file 1. Interview guides of focus group discussions.

Abbreviations

BCT: Behavior Change Technique; BMI: Body Mass Index; gLiFE: Group-based Lifestyle-integrated Functional Exercise; LiFE: Lifestyle-integrated Functional Exercise; MoCA: Montreal Cognitive Assessment; SRBAI: Self-Report Behavioural Automaticity Index; TUG: Timed Up and Go Test

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Authors' contributions

LR, FKG, SL, CPJ, CN, MN, MS: development of the semi-structured interview guide for the gLiFE and LiFE focus groups. LR, FKG, SL, CPJ, CN: study organization. MS, CB: development of the grand proposal for the LiFE-is-LiFE trial. LR, FKG, SL: conduction of focus group interviews. LR: data transcription. LR, FKG, SL: data analysis. LR, FKG: draft of manuscript. LR, FKG, SL, CPJ, CN, MN, CB, LC, MS: critical revision of the manuscript for important intellectual content. All authors have read and approved the final manuscript.

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Availability of data and materials

The data used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

Ethical approval for the LiFE-is-LiFE trial was obtained from the Ethic Review Board of the Faculty of Behavioral and Cultural Studies at Heidelberg University (study site Heidelberg, document number Schwe2017 2/1–1), and from the Ethic Review Board of the University Hospital and Faculty of Medicine in Tübingen (study site Stuttgart, document number 723/2017BO2) which are both followed the policy and mandates of the Declaration of Helsinki. For the LiFE-is-LiFE trial, as well as for the focus group study, all participants provided written informed consent.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Publisher's Note

Publication IV

Carl-Philipp Jansen, Corinna Nerz, **Sarah Labudek**, Sophie Gottschalk, Franziska Kramer-Gmeiner, Jochen Klenk, Judith Dams, Hans-Helmut König, Lindy Clemson, Clemens Becker, & Michael Schwenk (2021). Lifestyle-integrated functional exercise to prevent falls and promote physical activity: Results from the LiFE-is-LiFE randomized non-inferiority trial. *International Journal of Behavioral Nutrition and Physical Activity, 18*(1), 1–12. https://doi.org/10.1186/s12966-021-01190-z

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RESEARCH

Open Access

Lifestyle-integrated functional exercise to prevent falls and promote physical activity: Results from the LiFE-is-LiFE randomized non-inferiority trial

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Abstract

Background: The 'Lifestyle-integrated Functional Exercise' (LiFE) program successfully reduced risk of falling via improvements in balance and strength, additionally increasing physical activity (PA) in older adults. Generally being delivered in an individual one-to-one format, downsides of LiFE are considerable human resources and costs which hamper large scale implementability. To address this, a group format (gLiFE) was developed and analyzed for its non-inferiority compared to LiFE in reducing activity-adjusted fall incidence and intervention costs. In addition, PA and further secondary outcomes were evaluated.

Methods: Older adults (70 + years) at risk of falling were included in this multi-center, single-blinded, randomized non-inferiority trial. Balance and strength activities and means to enhance PA were delivered in seven intervention sessions, either in a group (gLiFE) or individually at the participant's home (LiFE), followed by two "booster" phone calls. Negative binomial regression was used to analyze non-inferiority of gLiFE compared to LiFE at 6-month follow-up; interventions costs were compared descriptively; secondary outcomes were analyzed using generalized linear models. Analyses were carried out per protocol and intention-to-treat.

Results: Three hundred nine persons were randomized into gLiFE ($n = 153$) and LiFE ($n = 156$). Non-inferiority of the incidence rate ratio of gLiFE was inconclusive after 6 months according to per protocol (mean = 1.27; 95% CI: 0.80; 2.03) and intention-to-treat analysis (mean = 1.18; 95% CI: 0.75; 1.84). Intervention costs were lower for gLiFE compared to LiFE (-€121 under study conditions; -€212€ under "real world" assumption). Falls were reduced between baseline and follow-up in both groups (gLiFE: -37%; LiFE: -55%); increases in PA were significantly higher in gLiFE (+ 880 steps; 95% CI 252; 1,509). Differences in other secondary outcomes were insignificant.

Conclusions: Although non-inferiority of gLiFE was inconclusive, gLiFE constitutes a less costly alternative to LiFE and it comes with a significantly larger enhancement of daily PA. The fact that no significant differences were found in any secondary outcome underlines that gLiFE addresses functional outcomes to a comparable degree as LiFE.

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Advantages of both formats should be evaluated in the light of individual needs and preferences before recommending either format.

Trial registration: The study was preregistered under clinicaltrials.gov (identifier: NCT03462654) on March 12th 2018

Keywords: Fall prevention, Non-inferiority trial, Fall risk, Intervention costs, Physical activity promotion

Background

Tackling physical inactivity and mobility disability in the face of wide-spread sedentariness has been declared a paramount objective which is founded on the numerous positive effects on health and aging-associated morbidity in older persons [1, 2]. Physical activity (PA) further improves independence, increases participation, and enhances quality of life [3, 4]. However, PA comes with certain risks. Every transition and step increase the risk of falling, which holds true particularly when performed unsafely by older adults with low functional capacity [5–8]. Recommendations to increase PA in older persons have often neglected this potential trade-off. Especially walking has been recognized as a "hazardous" PA in older persons [9, 10]. Arguably, beneficial effects of high PA may outweigh this risk by maintenance or improvement of functional capacity and mobility in the midterm, but oversimplified recommendations for increasing PA may not be unconditionally appropriate for the older population. Novel interventions should therefore be tested looking at an increase of safe PA, being defined as, e.g., falls per one million steps or falls per distance walked [11]. This requires sensor-based measurements of PA and mobility alongside classical outcome assessments of functional performance and perceived function. In summary, interventions should increase PA and simultaneously prevent falls and fall-related injuries. Examinations of a combined endpoint of fall risk and activity have been proposed as the gold standard approach [11–13].

The 'Lifestyle-integrated Functional Exercise' (LiFE) trial is a landmark study in this respect, having looked at both PA and falls [14], although without combining these endpoints for analysis. The study had shown significant improvement of balance and strength capacity of older persons aged 70 + years and further promoted an increase of PA [15]. A possible downside of LiFE in certain settings is that it is delivered individually by therapists in seven home visits. This comes with considerable human resources and costs. A smaller pilot trial from Canada raised the idea that a group-based LiFE format may be similarly effective [16]. This was supported by findings from a feasibility study evaluating the group-based LiFE (gLiFE) program used in this trial [17]. The economical assumption, that a group format could be less costly, as well as the group format's effectiveness in terms of the abovementioned combined endpoint have yet to be investigated.

Therefore, a non-inferiority trial was carried out to evaluate whether a group-based LiFE (gLiFE) program is not less effective than the original LiFE program (LiFE) by more than an acceptable amount while being less costly in terms of intervention costs. The acceptable amount is a predefined non-inferiority margin for the treatment effect in the trial's primary outcome [18]. Non-inferiority investigations require that the reference treatment's efficacy is established [18]. Given the high quality of the LiFE trial and the positive effects found [14], we considered this prerequisite confirmed.

Primary objectives of this study were 1) to compare non-inferiority of gLiFE compared to LiFE in reducing activity-adjusted fall incidence; and 2) to compare intervention costs of both formats. The corresponding hypotheses were that gLiFE is not less efficacious than LiFE in reducing activity-adjusted fall incidence, and that its delivery is less costly compared to LiFE. The secondary objective was to compare effectiveness of both formats regarding functional (dis-)ability, adherence, motor capacity, fall-related outcomes, fear of falling, balance confidence, and adverse events.

Methods

Study design

This study ("LiFE-is-LiFE") was a multi-center, single-blinded, randomized non-inferiority trial conducted in Heidelberg and Stuttgart, Germany. The full study protocol is available elsewhere [19]. The study was preregistered under clinicaltrials.gov (identifier: NCT03462654) on March 12th 2018. Reporting in this article is aligned with the CONSORT extension in non-inferiority trials [18] [see CONSORT checklist, Additional file 3].

In addition to baseline assessment, follow-up assessments were carried out six and twelve months after intervention start (reference was the date of the first (g)LiFE session), with a tolerance of ± 2 weeks.

Participants and eligibility criteria

For recruitment purposes a list of all persons aged 70 + was drawn from municipality registries in both cities. Persons were drawn consecutively in waves of between 250 and 1.000 persons and contacted between April

2018 and July 2019 by mail. If interested, participants could contact the study sites for a first eligibility screening by telephone. In case of a positive telephone screening, an inhouse screening was scheduled. Participant flow is depicted in Fig. 1. To be included in the study, participants had either a) experienced at least one injurious or more than one non-injurious fall in the year prior to study participation according to self-report, or b) were designated as having high risk of falls when indicating self-perceived balance decline and needing ≥ 12 s for the "Timed Up-and-Go" (TUG) [20] test. Those who already exercised more than once per week or indicated to carry out more than 150 min of moderate to vigorous PA per week were excluded. A detailed list of further exclusion criteria is provided in the study protocol [19].

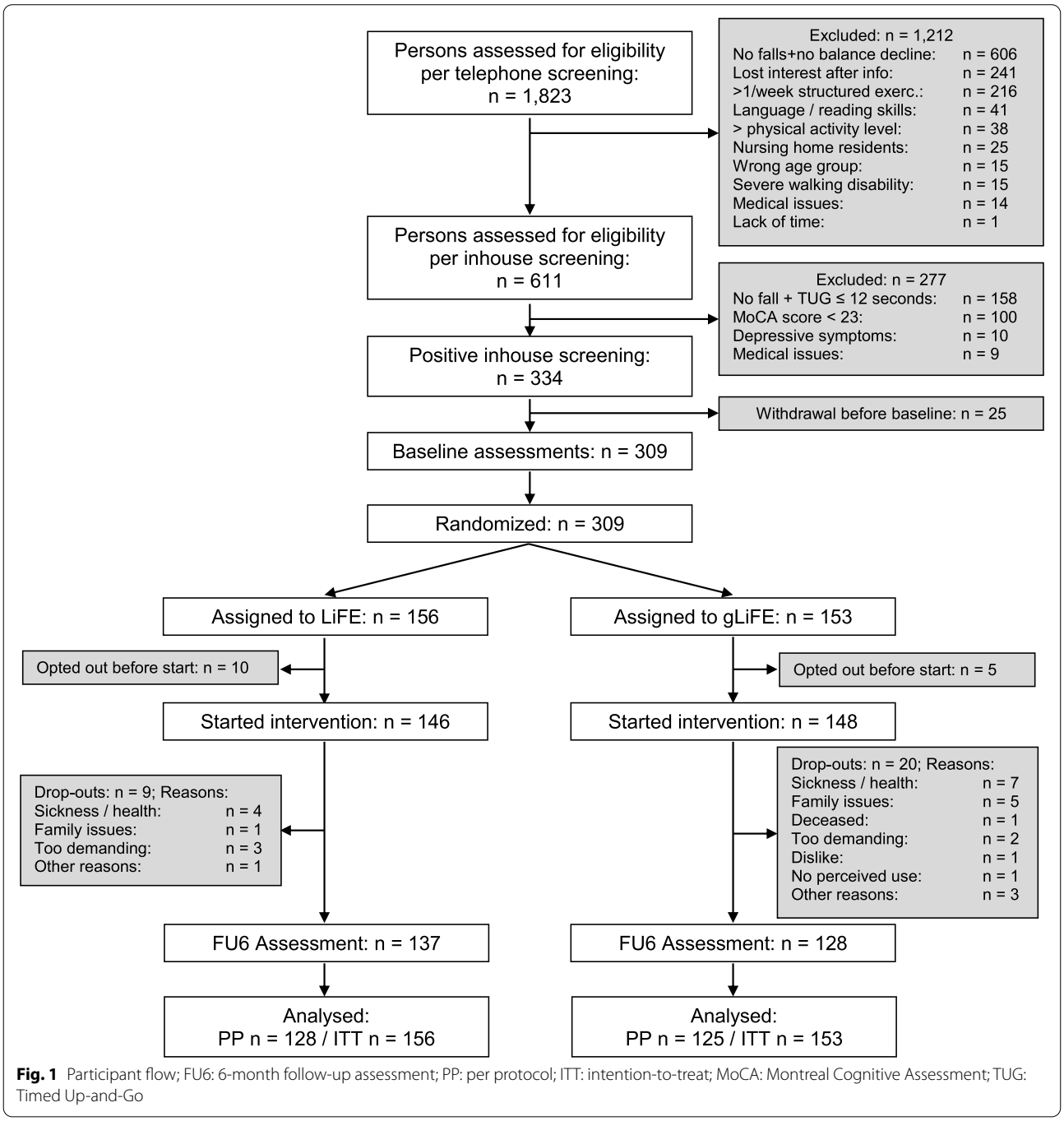

Fig. 1 Participant flow; FU6: 6-month follow-up assessment; PP: per protocol; ITT: intention-to-treat; MoCA: Montreal Cognitive Assessment; TUG: Timed Up-and-Go

Randomization and blinding

Participants were randomized after baseline assessment into one of the two intervention arms through block-randomization. Apart from block sizes, randomization was concealed, i.e., staff was not aware of the sequence before randomization. Randomization and group assignment was carried out by the study site coordinators (CPJ, CN) in an externally managed database without possibility to alter group allocation afterwards. In case of withdrawal from intervention, participants were still eligible for follow-up assessments. Assessors were blinded to group allocation at all times.

Intervention programs

A detailed description including a TIDieR checklist of both intervention formats is included in the study protocol [19]. In the LiFE program, balance and strength activities as well as general PA promoting activities are embedded into everyday tasks and routines, with the overall aim to integrate them in a way that these activities can be performed multiple times a day [14]. As there was no standardized group format of the LiFE program available, gLiFE had been developed according to Medical Research Council guidelines [21] and piloted in advance to the intervention start [17]. In both intervention arms, intervention components were taught in accordance with the LiFE trainer's manual [15], including strength and balance activities as well as strategies to enhance physically active behavior and to habitualize activities as part of individual daily routine. LiFE and gLiFE were delivered in seven sessions within eleven weeks, either in a group (gLiFE) or at the participant's home (LiFE), followed by two booster phone calls in week four and ten after the last intervention session. During the intervention sessions a total of seven balance activities, seven strength activities for the lower extremities, and two PA promoting activities were delivered. To help participants establish a LiFE routine as part of their daily life, they learned how to independently select, execute, and adapt intensity of activities, and how to identify appropriate daily situations in which LiFE activities can be integrated. gLiFE group sessions were scheduled for two hours and held by two trainers with a maximum of 12 participants; LiFE sessions lasted approximately one hour and were delivered by one trainer. Trainers were either physio therapists, sports scientists, health psychologists, or occupational therapists who had attended a two-day workshop prior to the start of the intervention delivery, including a certification test.

Outcomes

Primary outcomes

Combined endpoint: Falls adjusted for PA. To measure PA, "activPAL4™ micro" accelerometers (PAL Technologies Ltd., Glasgow, Scotland) were attached to participants' central front thigh at baseline, 6-, and 12-month follow-up to continuously measure PA under "free-living" conditions for seven days (24 h), i.e., activPALs were posted back to the respective study centers no earlier than the start of the ninth day of measurement. The sensor was wrapped in a nitrile finger cot fixed with a waterproof, adhesive, transparent film. The device has shown good to excellent reliability and validity [22]. If the device was removed earlier, data were used if at least two weekdays and the Sunday of the respective week were fully captured [23]. Given that walking activity can be seen as the most hazardous PA when it comes to risk of falling [9, 10], PA exposure was operationalized as mean steps/day.

Falls were defined as "an unexpected event in which the participant comes to rest on the ground, floor, or lower level" [24] and were recorded using a monthly falls calendar sent back by use of preaddressed and prestamped envelopes. In case of a fall, information on location, date, time, injuries, subsequent treatment related to the fall, and movement during which the person has fallen had to be provided on the calendar sheet. Following recommendations of Gillespie et al. [25], falls were followed-up via telephone calls to ascertain additional information and to determine the current health status of the person.

Intervention costs. Intervention costs were calculated as costs per participant for each group (LiFE/gLiFE). Personnel and material costs, trainers' and participants' travel expenses, and room rent were taken into account. The average group size of gLiFE sessions was 7.9 persons. The duration of the sessions (including time for travel and preparation) resulted in 1.8 (LiFE) and 3.0 (gLiFE) personnel hours per session. Personnel costs per hour were derived from the German wages agreement for civil services 2018 ("TVöD" salary level E13 and E10). Costs for materials, manuals, and working books were considered. Moreover, a room rent of €50 per day for the trainer workshop or per gLiFE session in one of the study centres was also taken into account. In the other study centre, a suitable room was available on site for the gLiFE sessions, therefore no room rent was incurred there.

Since study conditions deviate from conditions in case of an implementation in the "real world", interventions costs were also calculated for another scenario, based on assumptions that the project team considers to most realistically represent the implementation conditions. In this "real world" scenario, it was assumed that 20 trainers with a salary according to "TVöD" salary level E8 participate in the trainer workshop. It was assumed that

on average 12 persons attend the gLiFE sessions and that each gLiFE trainer pair would conduct 12 training sessions per week, while one LiFE trainer could conduct 15 sessions in the same time. The duration of the LiFE/gLiFE sessions (including time for travel and preparation) and phone calls were assumed to be 2.0 h/2.5 h and 0.5 h, respectively. For both interventions, no room rent was assumed. Furthermore, each trainer or trainer pair was assumed to have their own material set. The data and assumptions underlying the calculations of each scenario are summarized in an additional table [see Additional file 1].

Secondary outcomes

Physical activity. Mean steps/day were assessed to serve as offset variable in the primary outcome analysis to adjust falls for PA, and as PA outcome in itself.

Fall outcomes. Falls were assessed and defined according to Lamb et al. [24], that is, number of falls, fall rate per (half) person year, time to event (either fall or end of observation), number of fallers, and frequent fallers (i.e., more than one fall in the past six months). Fall consequences were categorized into minor, moderate or serious injuries according to a standardized system incorporating symptoms as well as medical care use [26].

Motor capacity. Gait performance was measured in terms of 7 m gait speed at comfortable and fast pace. The 30 s chair rise was used to evaluate functional leg strength [27]. Static balance was assessed using the adjusted eight level balance scale developed by Clemson et al. [14].

Functional (dis-)ability. The Late Life Function and Disability Instrument (LLFDI) was used to assess participants' difficulties in performing 32 different upper and lower extremity physical activities and actions as well performance of another 16 socially defined life tasks.

Adherence. We followed the consensus agreement by Hawley-Hague et al. [28] who recommend reporting adherence in terms of completion (attendance of at least > 75% of sessions is defined as completion [28]), attendance (percentage of sessions attended out of the actual number of sessions), and duration adherence (adherence to predefined LiFE activities at home, assessed using the Exercise Adherence Rating Scale (EARS) [29]). The EARS ranges from 0 to 24.

Fear of falling and balance confidence. Participants' fear of falling was assessed using the Short Falls Efficacy Scale-International [30], a self-rating scale including 7 items ranging from 'not at all concerned' (1 point) to 'very concerned' (4 points) and resulting in values between 7 ('not concerned about falling') and 28 points ('very concerned about falling'). The Activities-specific Balance Confidence Scale (ABC) was used to measure participants' confidence in maintaining their balance while performing certain daily activities.

For participants' characteristics, age, sex, body-mass index, number of medications, number of comorbidities, falls in the past six months, and cognitive status (Montreal Cognitive Assessment) were assessed.

Sample size and non-inferiority margin

Sample size was calculated based on 12 month data from the original LiFE study [14]; information on this calculation can be found in the study protocol [19]. As outlined in the limitations section COVID-19-induced changes have been made to the methods used for the present analyses. We used 6-month instead of 12-month data to determine non-inferiority of the primary outcome falls per PA. However, we kept the non-inferiority margin (Δ) as stated in the study protocol [19], that is, we accept a 20% difference in this outcome as a comparable reduction. As intervention costs of gLiFE are expected to be lower than of LiFE, no non-inferiority margin is defined for this outcome.

Statistical analyses

The analyses were carried out according to both the intention-to-treat principle (ITT) and the per-protocol principle (PP) to determine the robustness of the results due to missing values [31]. As dates were fixed for the gLiFE sessions, it was expected that some participants might be unable to attend all seven sessions. Therefore, attendance of a minimum of five sessions per participant was preset to assign participants to the PP sample. In accordance with the ITT principle, all randomized participants who completed baseline assessment were included, regardless of whether they had completed the intervention or prematurely dropped out of the study. In addition to missing information due to drop-out, there was occasional missing information in cases that otherwise completed the follow-up assessment. Overall, the percentage of missing values varied between 0 and 17% across different variables. As imputation of missing values is recommended for missing rates above 5% [32], missing data were imputed using multiple imputation by chained equations (MICE) with predictive mean matching as imputation method [33]. In total, 10 datasets were created based on data from baseline and 6-months' follow-up assessments and analysed separately. Rubin's rules [34] were applied to pool results from each dataset.

Negative binomial regression was used to compare incidence rate ratios (IRR) of falls between gLiFE and LiFE,taking into account possible overdispersion. In the model for the combined endpoint–falls per PA–mean steps/day were log-transformed and incorporated as exposure variable (offset). Confidence intervals

for explorative comparison of changes between baseline and 6-month follow-up in secondary outcomes were obtained using a generalized linear model with repeated measures.

For the primary outcome, non-inferiority was indicated if the upper limit of the two-sided 95% confidence interval (CI) for gLiFE remained below the relative margin (Δ) of 20% from LiFE (IRR = 1.20).

Analyses were performed using SPSS (IBM Corp. Released 2020. IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp). Multiple imputation of missing values was performed using STATA/SE 16.0 (StataCorp. 2019. Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC).

Results

Participant flow and baseline characteristics

We randomized 309 persons from June 2018 to July 2019 into gLiFE ($n = 153$) and LiFE ($n = 156$), of which 15 persons dropped out before the start of the intervention. At six months, 44 observations (14.2%) were lost to follow-up, $n = 25$ in gLiFE (16.3%) and $n = 19$ in LiFE (12.2%), respectively. Of the envisaged sensor-based 7-day PA measurement, at least 6 full days were completed by 99.0% of the participants at baseline and 98.8% at follow-up. Similarity of baseline values indicates successful randomization (Table 1). The majority of participants was female; on average, participants were cognitively intact, were moderately active, had mediocre motor function, and rather low fear of falling. No study-associated serious adverse events were reported. Of the 3 study-associated adverse events, all had mild consequences: one fall occurred on the way to an assessment (LiFE), one on the way to a gLiFE session, and one during a participant's demonstration of his LiFE execution at home while a trainer was present (LiFE).

Table 1 Participant characteristics at baseline according to ITT analyses

N (mean ± SD)	All *N* = 309	LiFE *N* = 156	gLiFE *N* = 153
Age, years	78.8 ± 5.3	78.8 ± 5.2	78.7 ± 5.4
Sex, n (%) female	227 (73.5)	115 (73.7)	112 (73.2)
BMI [kg/m^2]	27.2 ± 4.9	27.7 ± 5.0	26.8 ± 4.7
No. of medications	4.9 ± 3.4	5.0 ± 3.3	4.8 ± 3.4
No. of comorbidities	2.5 ± 1.6	2.5 ± 1.5	2.5 ± 1.6
MoCA Score	26.0 ± 2.0	26.1 ± 2.0	25.9 ± 2.0
No. of steps/day	5,659 ± 2,919	5,778 ± 3,009	5,538 ± 2,828
No. of falls p.p. in past 6 months	0.66 ± 1.1	0.66 ± 1.1	0.65 ± 1.1
% of fallers in past six months	126 (40.8)	63 (40.4)	63 (41.2)
LLFDI Function	57.3 ± 7.9	57.4 ± 8.0	57.3 ± 7.9
LLFDI Frequency	49.4 ± 4.3	49.3 ± 4.2	49.5 ± 4.4
LLFDI Disability	70.7 ± 12.0	71.7 ± 12.3	69.6 ± 11.5
Gait speed comfortable [m/s]	1.03 ± 0.20	1.03 ± 0.20	1.03 ± 0.21
Gait speed fast [m/s]	1.40 ± 0.32	1.37 ± 0.29	1.43 ± 0.35
30 s Chair Stand	9.1 ± 3.9	9.2 ± 3.8	9.0 ± 3.3
8 Level Balance Scale	4.3 ± 1.5	4.2 ± 1.5	4.4 ± 1.4
Short FES-I	10.4 ± 3.0	10.4 ± 3.1	10.3 ± 3.0
ABC Scale	75.3 ± 16.8	75.0 ± 17.6	75.5 ± 16.9

ABC Scale Activities-specific Balance Confidence Scale, *BMI* body mass index, *CI* confidence interval, *FES-I* Falls Efficacy Scale International, *ITT* intention-to-treat, *LLFDI* Late Life Function and Disability Instrument, *max* maximal, *MoCA* Montreal Cognitive Assessment, *No.* Number, *p.p.* per person, *SD* standard deviation, *TUG* Timed Up-and-Go

Primary outcomes

Combined endpoint: Falls adjusted for physical activity

Compared to LiFE, gLiFE had an incidence rate ratio of 1.07 (95% CI: 0.73; 1.57) at baseline and of 1.27 (95% CI: 0.80; 2.03) at 6 months according to PP analysis. When applying ITT analysis, IRRs at baseline (1.04; 95% CI: 0.72; 1.50) and 6 months (1.18; 95% CI: 0.75; 1.84) were smaller (Fig. 2). In both cases, non-inferiority was inconclusive due to upper confidence intervals crossing the 20% margin (Δ) at 6 months. This means there was a non-significant difference in the risk of experiencing a fall for gLiFE compared to LiFE participants. When subtracting the initial baseline difference of 7.3% (4.1%), the changed IRR between both groups remains at 20% (14%).

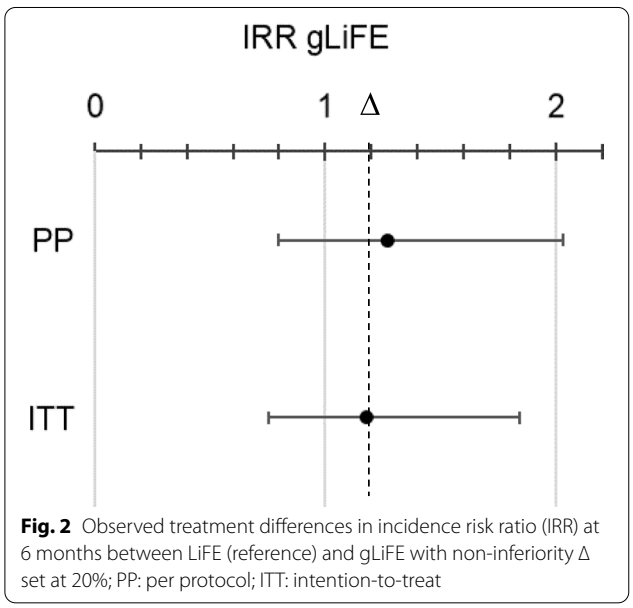

Fig. 2 Observed treatment differences in incidence risk ratio (IRR) at 6 months between LiFE (reference) and gLiFE with non-inferiority Δ set at 20%; PP: per protocol; ITT: intention-to-treat

Intervention costs

Under study conditions the total intervention costs per participant amounted to €350.10 for LiFE compared to €229.93 for gLiFE. This corresponded to a cost advantage of €121.17 for gLiFE. This cost advantage mainly resulted from a difference in personnel costs for trainers. In contrast, costs for room rent and travel expenses were marginally higher for gLiFE than LiFE with €23.45 and €17.92, respectively. Under "real world" assumptions, average costs per gLiFE participant were €120.58 compared to €332.08 per LiFE participant, resulting in a cost difference of €211.51 in favour of gLiFE. Again, this was mainly due to a difference in personnel costs. Intervention costs are summarized in table S2.

Secondary outcomes

Physical activity

Both groups increased their amount of steps/day between baseline and follow-up (Table 2). The increase in the gLiFE group was significantly larger than in the LiFE group in both PP (gLiFE to LiFE: + 880 steps; CI 252; 1,509) and ITT (gLiFE to LiFE: + 844; CI 176; 1,512) analyses. gLiFE participants increased their steps/day from 5,530 (SE 237); in LiFE, the increase from 5,880 (SE 255) was about a third (35,5%) of the increase in the gLiFE group according to ITT (PP: 30,5%).

Fall outcomes

According to ITT analyses, 109 falls (PP: 100) were recorded; 49 in LiFE and 60 in gLiFE participants between baseline and 6-month follow-up. Of these, 29 persons fell once in LiFE and 27 in gLiFE; 9 persons in LiFE and 15 in gLiFE fell at least twice (maximum of 4 falls in each group), that is, there were 38 fallers in LiFE and 42 in gLiFE. The incidence of falls per half person year (ITT) in LiFE was 0.30 (SE 0.05) and 0.40 (SE 0.06) in gLiFE (PP; gLiFE: 0.41, SE 0.06; LiFE: 0.30, SE 0.05). The time to event (first fall) and observation time were similar in both groups (median = 180 days). Comparing the number of falls per half person year at baseline and 6 months, the incidence decreased about 37% (0.65 to 0.41) in gLiFE and 55% in LiFE (0.66 to 0.30) (ITT). Falls entailed mild (75%), moderate (18%), and severe (7%) consequences as per definition of Schwenk et al. [26].

Motor capacity

Results of motor capacity assessments are shown in Table 2. No significant differences in changes of motor capacity between groups were found for any of the measures, although improvement in gLiFE was larger in 30 s. chair rise (+ 1.00 vs. + 0.38 in LiFE) and 8 level balance scale (+ 0.25 vs. ± 0.00 in LiFE). LiFE participants showed somewhat larger improvement in comfortable gait speed (gLiFE + 0.03 m/s vs. LiFE + 0.04 m/s) and fast gait speed (gLiFE -0.02 vs. LiFE + 0.02). PP analyses did not alter these findings.

Functional (dis-)ability

According to LLFDI results, increase in both groups in the functional domain was comparable. Self-perceived function increased slightly from 57.3 (SE 0.6) to 59.2 (SE 0.8) in gLiFE and from 57.4 (SE 0.6) to 58.9 (SE 0.8) (ITT; mean difference 0.3; 95% CI: -1.33; 1.95; $p = 0.710$). Self-perceived disability improved from 69.6 (SE 0.9) to 71.2 (SE 1.1) in gLiFE and decreased from 71.7 (SE 1.0) to 70.8 (SE 1.0) in LiFE (ITT; mean difference 2.4; 95% CI: -0.71; 5.50) in favor of gLiFE. PP analysis did not alter these findings.

Adherence

Both groups had a high proportion of completers; 99% of LiFE and 88% of gLiFE participants took part in more than 75% of the sessions. Under ITT stipulations, those numbers expectedly dropped to 91 and 78%, respectively. With 7.8 sessions on average, gLiFE participants attended significantly less sessions than LiFE participants with 8.7 sessions (PP: 95% CI: -0.68; -1.12). ITT analysis did not change this finding. Duration adherence according to EARS scores were significantly lower in the gLiFE group: 14.9 in gLiFE compared to 16.0 in LiFE (95% CI: -0.01; -2.18). Again, ITT analysis did not affect this finding.

Fear of falling and balance confidence

Fear of falling decreased in both groups to a comparable level. In gLiFE, it dropped from 10.3 to 9.5 (change of -0.8; SE 0.2); in LiFE, it dropped from 10.4 to 9.6 (change of -0.8; SE 0.2). The between-group difference in this change was not significant (95% CI: -0.62; 0.62). Balance confidence values (ABC scale) were increased in both groups, however, differences in these changes were not significant (-2.62; 95% CI: -6.09; 0.84). PP analyses did not alter these findings.

Discussion

In the LiFE-is-LiFE trial it was investigated (1) whether gLiFE as a group format of the LiFE program was non-inferior to the individually delivered, original LiFE format in terms of activity-adjusted fall risk, and (2) whether both formats differed in their effect on PA and several function- and adherence-related outcomes. To the best of our knowledge, there has not been any direct comparison of a group format and an individually delivered format of the same intervention program so far; even less one including an economic evaluation.

Table 2 Baseline and 6-month secondary outcome data and between-group comparison

mean ± SE	LiFE		gLiFE		Between-group difference (95% CI) gLiFE vs. LiFE	
	PP	ITT	PP	ITT	PP	ITT
Mean steps/day						
Baseline	5,880 ± 255	5,778 ± 250	5,530 ± 237	5,538 ± 234		
Post	6,266 ± 254	6,242 ± 257	6,797 ± 264	6,847 ± 257		
Change	*386 ± 227*	*465 ± 257*	*1,266 ± 213*	*1,309 ± 225*	*880 (252; 1,509) p = .007*	*844 (176; 1,512) p = .015*
LLFDI function						
Baseline	57.4 ± 0.68	57.4 ± 0.64	57.4 ± 0.63	57.3 ± 0.64		
Post	58.9 ± 0.75	58.9 ± 0.76	59.1 ± 0.76	59.2 ± 0.77		
Change	*1.5 ± 0.48*	*1.5 ± 0.55*	*1.7 ± 0.51*	*1.9 ± 0.57*	*0.18 (-1.23; 1.58) p = .807*	*0.31 (-1.33; 1.95) p = .710*
LLFDI frequency						
Baseline	49.5 ± 0.34	49.3 ± 0.33	49.8 ± 0.38	49.5 ± 0.35		
Post	50.3 ± 0.41	50.1 ± 0.40	50.2 ± 0.41	50.0 ± 0.42		
Change	*0.8 ± 0.29*	*0.8 ± 0.30*	*0.4 ± 0.30*	*0.48 ± 0.34*	*-0.47 (-1.32; 0.38) p = .279*	*-0.29 (-1.25; 0.66) p = .546*
LLFDI disability						
Baseline	71.8 ± 1.03	71.7 ± 0.99	69.3 ± 0.94	69.6 ± 0.93		
Post	70.8 ± 1.01	70.8 ± 1.05	71.3 ± 1.14	71.2 ± 1.10		
Change	*-1.0 ± 1.05*	*-0.9 ± 1.10*	*1.9 ± 1.04*	*1.5 ± 1.08*	*2.87 (-0.05; 5.79) p = .054*	*2.40 (-0.71; 5.50) p = .132*
FESI						
Baseline	10.4 ± 0.27	10.4 ± 0.25	10.3 ± 0.25	10.3 ± 0.24		
Post	9.7 ± 0.23	9.6 ± 0.23	9.4 ± 0.22	9.5 ± 0.22		
Change	*-0.8 ± 0.24*	*-0.8 ± 0.24*	*-0.9 ± 0.21*	*-0.8 ± 0.22*	*-0.14 (-0.76; 0.49) p = .669*	*0.00 (-0.62; 0.62) p = .996*
ABC						
Baseline	74.7 ± 1.48	75.0 ± 1.41	75.6 ± 1.36	75.5 ± 1.36		
Post	78.8 ± 1.25	79.1 ± 1.21	77.7 ± 1.31	77.0 ± 1.30		
Change	*4.1 ± 1.16*	*4.1 ± 1.14*	*2.1 ± 1.27*	*1.5 ± 1.32*	*-1.94 (-5.31; 1.43) p = .259*	*-2.62 (-6.09; 0.84) p = .138*
30 s chair rise						
Baseline	9.1 ± 0.32	9.2 ± 0.31	9.0 ± 0.27	9.0 ± 0.27		
Post	9.6 ± 0.36	9.5 ± 0.34	10.0 ± 0.38	10.0 ± 0.40		
Change	*0.49 ± 0.31*	*0.38 ± 0.30*	*1.10 ± 0.31*	*1.00 ± 0.34*	*0.56 (-0.26; 1.38) p = .180*	*0.63 (-0.25; 1.51) p = .164*
8 level balance scale						
Baseline	4.2 ± 0.13	4.2 ± 0.12	4.4 ± 0.12	4.4 ± 0.11		
Post	4.2 ± 0.13	4.2 ± 0.13	4.6 ± 0.14	4.6 ± 0.14		
Change	*0.0 ± 0.12*	*0.0 ± 0.13*	*0.2 ± 0.14*	*0.25 ± 0.13*	*0.21 (-0.58; 0.15) p = .248*	*0.20 (-0.17; 0.58) p = .290*
Gait speed normal						
Baseline	1.04 ± 0.02	1.03 ± 0.02	1.05 ± 0.02	1.03 ± 0.02		
Post	1.07 ± 0.02	1.07 ± 0.02	1.07 ± 0.02	1.06 ± 0.02		
Change	*0.04 ± 0.01*	*0.04 ± 0.01*	*0.02 ± 0.02*	*0.03 ± 0.02*	*-0.01 (-0.05; 0.02) p = .458*	*-0.01 (-0.05; 0.03) p = .651*
Gait speed fast						
Baseline	1.38 ± 0.02	1.37 ± 0.02	1.44 ± 0.03	1.43 ± 0.03		
Post	1.40 ± 0.03	1.39 ± 0.03	1.43 ± 0.03	1.41 ± 0.03		
Change	*0.02 ± 0.02*	*0.02 ± 0.02*	*-0.01 ± 0.02*	*-0.02 ± 0.02*	*-0.03 (-0.08; 0.02) p = .243*	*-0.04 (-0.09; 0.02) p = .212*

Primary outcomes

For the main outcome, activity-adjusted fall risk operationalized as IRR, non-inferiority was not confirmed as the upper bound of the two-sided 95% confidence interval crossed the predefined 20% non-inferiority margin. Per definition, this means that non-inferiority of gLiFE is 'inconclusive' [18]. One reason for this could be that we used 6-month instead of 12-month data, and that differences at 6 months are of different nature than at 12 months. As there are less fall events within 6 than within 12 months, there is a higher risk of random error which could have influenced the point estimate. From an intervention perspective, the LiFE group was under more direct and closer individual supervision than gLiFE participants during the intervention phase, which might come with more problems to independently conduct and adapt LiFE activities as compared to gLiFE participants in the long term. Unlike LiFE participants who had direct suggestions and support, gLiFE participants had learnt to implement LiFE activities in their own way at home right from the start. We also see that the mean IRR is very close to the 20% margin, suggesting that the actual difference could be close to these 20%.

Comparing the reduction in overall incidence of falls between baseline and follow-up, both groups in the present trial reduced their fall incidence to a great extent. Despite the fact that fall incidence was already low in our sample at baseline, these reductions were greater (37% gLiFE; 55% LiFE) than in the LiFE group in the reference trial by Clemson et al. (22%) [14].

Regarding the second primary outcome, intervention costs of several exercise-based fall prevention programs have already been determined as part of economic analyses [35]. However, such economic analyses have not been performed for the LiFE program, yet, despite the high effectivity of this program for reducing falls and increasing PA [14]. This is of interest for potential payers of the intervention in case of implementation. Our findings highlight that gLiFE was associated with lower intervention costs compared to LiFE while at the same time reducing falls in both formats, making it an attractive alternative from a payer's and individual's perspective. The size of the cost advantage depended primarily on the ratio of participants to trainers. Therefore, the cost advantage was particularly pronounced in the "real world" scenario, which assumed a higher number of participants per group. Moreover, the total intervention costs per participant depended on the trainers' salary or the number of groups each trainer/trainer pair supervises. Hence, there is not only one possible scenario of the "real world", but the assumptions made in this study were found to be the most realistic by intervention experts. For an informed recommendation regarding implementation, other health-care utilization costs beside intervention costs must be examined in relation to the health effects. An economic evaluation regarding the cost-effectiveness of gLiFE will assist in making implementation recommendations and is part of further analyses [36].

Secondary outcomes

In general, the main idea of the LiFE program–to promote safe PA and simultaneously improve motor function [15]–was confirmed. PA, operationalized as walking activity for our study purpose, was increased in both groups. With 23%, this increase was significantly higher in gLiFE than in LiFE with 7%. Walking has been identified as key factor in promoting PA and health [37] and steps/day are a tangible activity goal for both participants and trainers [38]. Increased walking activity over more than 1,000 steps/day comes with lower risk of all-cause mortality as well as cardiovascular disease morbidity and mortality [39]. Hence, on average gLiFE seems better suited to evoke activity-related health benefits. This is further supported in that other studies have shown much lower pre-to-post intervention changes in steps/day, averaging around 800 steps change in older, mainly community-dwelling adults [40]. With an average between 5,500 and 5,800 steps/day in both groups at baseline, our sample was slightly more active than in studies with large samples of men and women of similar age [7, 41], indicating at least moderate activity levels. The examination of mechanisms of action in LiFE and gLiFE do not provide evidence for the superiority of gLiFE in affecting psychological determinants which are assumed to translate into behavioral changes [42]. However, it is possible that gLiFE participants profited of the group program in a way we did not capture with our measurements, e.g., through comparison with peers.

For other secondary outcomes, there were no significant differences in changes over six months between both groups. Descriptive data showed somewhat larger improvement over 6 months in gLiFE for LLFDI disability, but not for any other secondary measure. The difference between comfortable and fast gait speed at baseline indicates that there is a notable reserve in functional capacity in our sample. Taking into account that gLiFE participants had significantly lower attendance rates and duration adherence, it seems that the 'dose' given to gLiFE participants was still sufficient to achieve effects comparable to LiFE.

The LiFE intervention was delivered similarly to the reference trial by Clemson and colleagues [14], but underwent small organizational changes, which were needed to align LiFE and gLiFE contents in our study (this is further discussed elsewhere [17, 19]). Duration adherence at 6 months according to EARS was medium to good

in both groups with mean values confirming adherence to their plans. LiFE participants had a higher adherence at 6 months, which could be due to higher intervention attendance rates. The fact that attendance was significantly higher in LiFE than in gLiFE was not surprising as the group session schedule was predetermined and not movable whereas individual appointments in LiFE could easily be moved according to participants' requirements. One factor that might have boosted effectiveness of gLiFE is social support by other group members, which was found to be supportive of engagement in exercise and PA [43]. According to an extensive review on exercise interventions to prevent falls, however, there is no difference in effect based on intervention format (group vs. individual) [44]. Further analyses are needed to determine which characteristics of both formats are responsible for differences in both groups' outcomes.

Strengths and limitations

Results of the present study need to be interpreted in the light of several strengths and limitations. Non-inferiority trials are becoming more frequent, aiming to establish interventions' non-inferiority over another treatment [19]. Instead of developing new interventions which then have to undergo extensive scientific evaluation, it seems worth looking at already established intervention programs such as LiFE. By adapting or refining existing interventions, their feasibility and cost-effectiveness could be improved, which in turn would come with advantages for participants and payers equally. The LiFE program has the benefit of being carried out at participants' homes, which entails fewer burdens to physical exercise than conventionally delivered structured exercise. Many of those burdens, especially those being highlighted by older adults [45] do not apply in the LiFE program (e.g., bad weather, lack of time). Having shown that both modes of delivery come with meaningful health benefits such as enhanced PA, gLiFE could now be made available also to those who prefer company of others. At the same time, those who prefer being on their own can be served as well. Another strength is that activity-adjusted falls were assessed using highly reliable methods. For fall documentation, participants completed fall calendars [46]; PA was assessed using highly reliable sensors over a full week with very few incomplete measurements (< 2%). Moreover, we followed the extended consort statement of 2010 for non-inferiority trials, thus abiding by clear reporting and interpretation standards. Lastly, data analyses were carried out for both PP and ITT including multiple imputation [32].

Despite many strengths, some limitations are to be considered. As pandemic circumstances had a strong impact on older adults' habitual PA and overall movement behavior [47] it is expected that 12-month follow-up data were highly biased. COVID-19 pandemic regulations began shortly after completion of the 6-month assessments, and about one third of the participants were not assessed regularly as part of 12-month follow-up within the specified time window. Attempts were therefore made to follow up any unscheduled assessment after re-opening of public structures following the lockdown. Therefore, we chose to deviate from the study protocol by evaluating non-inferiority based on 6-month instead of 12-month data. Moreover, pre-baseline falls data were assessed retrospectively for 6 months. Comparing 6-month follow-up fall data with baseline falls therefore is to be done very cautiously due to the different standard and sources of bias in falls assessment [24]. Due to the established effectiveness of the LiFE program [14], no control group was included in this trial. Natural progression of IRRs without intervention therefore cannot be quantified. Compared to the Australian LiFE study [14], the present sample was somewhat younger (-4 years), had a higher proportion of women (+ 14%) and less falls in the past (0.66 per person and half year compared to 2.13 per person and year in Clemson et al.), which limits comparability with our findings.

Conclusions

Non-inferiority of gLiFE's reduction of falls compared to LiFE was inconclusive, while its increase in walking activity was significantly higher than in LiFE, which shows its large potential especially in promoting PA. In the light of lower intervention costs compared to LiFE, gLiFE is an alternative from a payer's and individual's perspective. Our results suggest that both formats come with important effects and advantages, and that individuals should be given the opportunity to choose between both formats depending on their individual goals.

Abbreviations

ABC Scale: Activities-specific balance confidence scale; BMI: Body mass index; CI: Confidence interval; EARS: Exercise Adherence Rating Scale; FES-I: Falls Efficacy Scale International; gLiFE: Group-based Lifestyle-integrated Functional Exercise; IRR: Incidence rate ratio; ITT: Intention-to-treat; LiFE: Lifestyle-integrated Functional Exercise; LLFDI: Late-life function and disability instrument; MoCA: Montreal cognitive assessment; No.: Number; PA: Physical activity; p.p.: Per person; PP: Per protocol; SD: Standard deviation; SE: Standard error; TIDieR: Template for intervention description and replication; TUG: Timed Up-and-Go test.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12966-021-01190-z.

Additional file 1. Data and assumptions for the calculation of Intervention costs by scenario

Additional file 2. Intervention costs per participant for gLiFE and LiFE by scenario and cost category

Additional file 3. CONSORT Statement 2006 - Checklist for Non-inferiority and Equivalence Trials

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Authors' contributions
CPJ, CN, SL, JK, JD, HHK, LC, CB, and MS have made substantial contributions to the conception and design of this work; CPJ, CN, FKG, and SL have carried out data acquisition; CPJ, SL, SG, JK, JD, and MS have contributed to data preparation and analyses; all authors have contributed to interpretation of data and have drafted and revised this work substantially; all authors have approved the submitted version; all authors have agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature.

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Availability of data and materials
The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
Ethical approval was obtained for both sites: Heidelberg document number Schwe2017 2/1–1; Stuttgart document number 723/2017BO2. All participants gave written informed consent prior to participation The study is conforming to the respective policy and mandates of the Declaration of Helsinki.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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Publisher's Note

Publication V

Melissa J. Wolf, **Sarah Labudek**, Christoph Endress, Carl-Philipp Jansen, Corinna Nerz, Clemens Becker, Lindy Clemson, & Michael Schwenk (2022). *Participants' evaluation of the individual and group-based LiFE program: Results from the LiFE-is-LiFE trial.* [Manuscript submitted for publication in *Aging Clinical and Experimental Research*]. Network Aging Research, Heidelberg University.

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Keywords: lifestyle-integrated exercise, participant evaluation, group vs. individual training, older adults, falls

Abstract

Background: A resource-saving group-based version (gLiFE) of the Lifestyle-integrated Functional Exercise (LiFE) program was developed for large-scale implementation.

Aims: To examine 1) participant satisfaction with the two LiFE formats and program-specific aspects, 2) how evaluations changed over time, and 3) potential for program optimization.

Methods: Multi-center randomized trial; participants attended LiFE or gLiFE. Questionnaires on four thematic categories were completed after six (T1) and twelve (T2) months: overall evaluation, knowledge transfer, materials/contents, and program outcomes. Descriptive and inferential statistics were used to explore differences between both formats and within-group changes between T1 and T2.

Results: Participants (n_{LiFE}=126, n_{gLiFE}=126, M_{age}=78.6±5.2 years) reported positive perceptions of their format with small median deviations between formats (0.5 < IQR < 1). Highest evaluation scores were found for LiFE's one-to-one teaching style. LiFE participants reported greater helpfulness of planning strategies (p_{T1}=.002) and higher satisfaction with strength improvements (p_{T2}<.001) compared to gLiFE participants. No further significant differences between formats were found. At T2 compared to T1, LiFE participants rated integrability of activities significantly lower ($p_{T1/T2}$<.001) and helpfulness of discussing practice situations with a trainer higher ($p_{T1/T2}$<.001).

Discussion: The few differences between formats reveal useful implications for future refinement of both formats. Increasing the focus on LiFE's long-term maintenance and integrating stronger individual supervision in gLiFE should be considered.

Conclusion: LiFE and gLiFE were well perceived by participants and evaluations remained mostly stable over time. The present results extend previous findings regarding positive short and long-term participant perceptions and support gLiFE as an alternative to LiFE.

Introduction

Physical inactivity and falls have negative individual as well as health-economic consequences, such as reduced quality of life, increased morbidity, and higher treatment costs [1–3]. Multifactorial functional exercises targeting balance and muscle strength are recommended for reducing falls and health care costs in older adults [4, 5]. However, most "traditional" structured training approaches come with poor long-term adherence among participants [6]. For many older people, such conventional exercise programs are not attractive for several reasons [7].

The original Lifestyle-Integrated Functional Exercise (LiFE) program [8] is a one-to-one training delivered in seven home visits by a single trainer and uses a lifestyle-integrated approach in contrast to structured training. LiFE's aim is to increase physical activity and function while simultaneously reducing falls [9]. Participants learn how to embed functional balance and strength exercises into their daily routines and thereby form new, more active movement habits [10], and to manage their training individually.

In a large three-arm randomized study, LiFE showed higher adherence rates and greater improvements in balance and strength, as well as a significant reduction in the rate of falls compared to a structured training approach and controls [8]. However, the resource-intensive one-to-one training is not suitable for large-scale implementation in this form. To increase the reach of LiFE, a group-based version (gLiFE) was developed by Kramer and Labudek et al. [11] that is delivered in seven group sessions with two trainers and between eight and twelve participants. The large, multicenter LiFE-is-LiFE trial [12, 13] confirmed that gLiFE provides a less costly alternative to the LiFE program. The results on cost-effectiveness were consolidated in one further study [14] showing that gLiFE might be cost-effective with regard to increasing physical activity. Beyond economic aspects, it was found that gLiFE is associated with a significantly larger increase of daily physical activity [13]. A qualitative analysis on basis of a subsample of the LiFE-is-LiFE trial [13] showed high acceptability of both gLiFE and LiFE [15].

Building on this evidence, the present study aims to gain a deeper insight into LiFE and gLiFE from the participants' perspective. By involving users, we follow guidelines for the evaluation and refinement of complex health interventions [16, 17]. In accordance with these guideline recommendations, we examine LiFE and gLiFE participants' overall experiences and satisfaction, the individual and group-based delivery formats and their context of knowledge transfer, the specifically developed program content and material resources, and perceived outcomes from the participants' point of view [16]. Objectives of this paper were to investigate 1) how participants evaluate their satisfaction with the two LiFE formats in general and

program-specific aspects of LiFE and gLiFE, 2) how evaluations changed over time and 3) any potential for program optimization.

Materials and Methods

Study design and sample

This study contains secondary analyses of the multi-center, single-blinded, randomized non-inferiority "LiFE-is-LiFE" trial [13, 18]. The trial was conducted from June 2018 until August 2020. Main outcomes were activity-adjusted fall incidence and intervention costs at 6- and 12-month follow-up. Details on the study procedure and outcomes are described elsewhere [18]. The focus of this paper is to examine the participants' perspectives on overall evaluation, knowledge transfer, materials/contents and program outcomes.

Participants

Community-dwelling older adults, aged ≥ 70 years who were able to walk ≥ 200 meters with or without walking aid and were at risk of falling were included. Participants were recruited in Heidelberg (Network Ageing Research, Heidelberg, Germany) and Stuttgart (Robert Bosch Hospital, Stuttgart, Germany). After a two-step screening procedure, eligible participants signed informed consent and then underwent a baseline assessment, after which they were randomized into the LiFE and gLiFE format. Follow-up assessments were conducted six (T1) and twelve months (T2) after the first intervention session. Further information on study procedures, sample size calculation, and detailed inclusion and exclusion criteria is provided in the study protocol [13, 18].

Intervention

LiFE aims to reduce falls as well as fall-related outcomes and promote long-term physical activity in older people by integrating balance (e.g., "one leg stand") and strength (e.g., "squat") exercises as well as principles for increasing physical activity (i.e., "move more" and "sit less") into their daily routines [8]. New movement habits are created by linking LiFE activities to specific everyday situations (e.g. "standing on one leg while brushing teeth") [11, 19]. gLiFE had been developed based on LiFE to reduce resource use (e.g., trainer-participant ratio) and facilitate large-scale implementation. gLiFE is delivered in groups of 8-12 participants, led by two trainers who support interaction between group participants through group discussions and joint activity practice. In order to make LiFE feasible for the group setting, gLiFE entails modified psychological contents to promote behavior change and increase intervention success [11]. The Behavior Change Techniques (BCT) Taxonomy v1 [20] was applied to report the intervention strategies used in gLiFE. BCTs were also allocated to theories of behavior

change (shown in Table 1). While the activities can be performed directly in the specific situation in the participant's own environment in LiFE, gLiFE requires participants to visualize real-life practice situations. Both LiFE and gLiFE participants are instructed to form implementation intentions [21], i.e., "if-then" sentences to plan when and where to perform the LiFE activities, such as "If I make a phone call, then I do the tandem walk". Furthermore, there is specifically developed gLiFE material such as posters displaying the LiFE activities and principles as well as different aids for correct movement execution [11]. Program details of LiFE [9] and gLiFE [11] are described elsewhere. Online Resource 1 presents an overview of the similarities and differences between both formats.

Materials

The present analysis focuses on the questionnaire evaluating the participants' perspective on both LiFE formats, which was part of the follow-up assessment at T1 and T2.

The LiFE-is-LiFE trial research group [13, 18] developed two similar but program-specific questionnaires; one LiFE-version (23 items) and one gLiFE-version (25 items) (see Online Resource 2). Seven items were adopted from the acceptability questionnaire previously developed for evaluating LiFE in young seniors [10]. All items were presented with 6-point Likert-scales (e.g., 1 = "very unsatisfied" to 6 = "very satisfied"). The single items and their thematic allocation into four categories are described below.

Outcome measures

The Likert scales of all items are listed beneath Table 2.

Category 1: Overall evaluation. Overall rating (item 1), perceived safety when practicing during the home visit (item 2_{LiFE}), perceived safety when practicing during the group session (item 2_{gLiFE}), perceived safety when practicing alone at home (item 3), physical challenge (i.e., perceived intensity of the LiFE activities; item 4), integrability into daily life (item 5), appraisal of the other format (i.e., hypothetical participation in the other format; item $6_{LiFE/gLiFE}$).

Category 2: Knowledge transfer. Exchange with the trainer (item 7_{LiFE}), share experiences with other group members (item 7_{gLiFE}), repetition of activities at home (item 8_{LiFE}), repetition of activities during the group sessions (item 8_{gLiFE}), discuss activity situations with the trainer (item 9_{LiFE}), discuss activity situations with other participants (item $9a_{gLiFE}$), visualize the activity situation in the group (item $9b_{gLiFE}$), write down possible activity situations on posters (item $9c_{gLiFE}$), practicing directly in the specific situation with the trainer at your home (item 10_{LiFE}), practicing with people your age in a group setting (item 10_{gLiFE}).

Category 3: Materials/contents. Theoretical content about the LiFE program (item 11), "if-then" sentences for planning the LiFE activities (item 12), materials for learning how to perform the activities correctly (item 13), LiFE participant's manual (item 14) and the workbook (item 15).

Category 4: Program outcomes. Perceived improvements in balance (item 16), strength (item 17), and physical activity (item 18-19), satisfaction with results from the program (item 20), satisfaction with improvements in balance/strength/physical activity (item 21-23).

Statistical analyses

Statistical analyses were performed using SPSS version 26 (IBM, Armonk, NY, USA). Participant characteristics are reported as number of participants (*N*), percentage (%), median (*Mdn*), and interquartile range (IQR), as appropriate. Data from the Likert-scaled questionnaires were analyzed descriptively and reported as *Mdn* and IQR. As data were not normally distributed, analysis was carried out with nonparametric tests. The Mann-Whitney *U*-test was employed to test for statistical differences between LiFE and gLiFE participants in their program evaluation at T1 and T2. Comparisons between formats were calculated for a total of 16 items that were identical in the LiFE and gLiFE version of the questionnaire (e.g., item 22). Data for the program-specific items, which differed in wording or content (e.g., item 19_{LiFE}/item 19_{gLiFE}), were analyzed descriptively for T1 and T2. The Wilcoxon signed-rank test was applied for the comparison of results within the two formats at T1 and T2 (LiFE: 23 items, gLiFE: 25 items). We employed a Bonferroni correction to counter the effect of alpha inflation due to multiple testing, resulting in a p-value of $p < .003$ to indicate significant differences between formats and $p < 0.002$ for differences between follow-ups. For significant results, effect sizes were calculated using Pearson's correlation coefficient *r* [22] with $r = .5$ indicating a large effect, $r = .3$ a medium effect and $r = .1$ a small effect [23].

Results

Participant flow and characteristics

In the LiFE-is-LiFE trial [13], 309 participants were randomized into LiFE (n_{LiFE}=156) and gLiFE (n_{gLiFE}=153). In total, n_{LiFE}=137 and n_{gLiFE}=128 participants completed the T1 assessment. The questionnaire was filled out by n_{LiFE}=126 and n_{gLiFE}=126. All cases were included in the analysis for T1. At T2, n_{LiFE}=120 and n_{gLiFE}=120 participants filled out the questionnaire; all cases were included in the analyses again. Participant characteristics are shown in Table 1. Participants were predominantly female (76%) and overweight (mean BMI=27.2), according to the WHO classification [39], had a mean age of 78.6 years and 40.1% experienced a fall in the six months prior to baseline assessment.

Table 1: Participant characteristics at baseline

N (mean ± SD)	All N=252	LiFE N=126	gLiFE N=126
Age, years	78.6 ± 5.2	78.6 ± 4.9	78.7 ± 5.6
Sex, n (%) female	192 (76.2)	98 (77.8)	94 (74.6)
BMI [kg/m²]	27.2 ± 4.9	27.8 ± 5.1	26.6 ± 4.7
MoCA Score	26.0 ± 2.0	26.1 ± 2.0	25.9 ± 2.0
% of fallers in past 6 months	101 (40.1)	47 (37.3)	54 (42.9)
Frequency of falls in past 6 months	0.7 ± 1.2	0.6 ± 1.1	0.7 ± 1.2
Short FES-I	10.4 ± 3.1	10.5 ± 3.3	10.3 ± 3.0
Physical function (TUG, sec.)	13.4 ± 3.9	13.6 ± 4.0	13.2 ± 3.9
No. of steps/day	5,758 ± 2,923	5,8442 ± 3,046	5,655 ± 2,805

BMI: Body mass index, FES-I: Falls Efficacy Scale International; MoCA: Montreal Cognitive Assessment; SD: standard deviation; TUG: Timed Up-and-Go

Questionnaire results from the 6-month follow-up (T1)

Comparison between formats: Category 1 "overall evaluation" (T1)

At T1, differences between formats were not significant for any of the six items in this category (shown in Table 2). The descriptive data analysis shows that the gLiFE format achieved a somewhat higher *overall rating* compared to LiFE (see Table 2, Online Resource 3). The LiFE program was rated higher concerning *perceived safety while practicing during the home visits* and lower regarding *physical challenge*. Participants in both formats rated the *safety while practicing alone at home* both equally and highly. LiFE participants considered the *helpfulness of hypothetically practicing the LiFE program in a group* lower an gLiFE participants rated the *helpfulness of hypothetically practicing the LiFE program alone with the trainer at home* somewhat higher. IQR for the *appraisal of the other format* was IQR=2 in both formats indicating that opinions were more scattered compared to other items.

Comparison between formats: Category 2 "knowledge transfer" (T1)

Descriptive results in both formats showed overall higher evaluation scores (*Mdn*=5 and 6) compared to the other three categories (see Table 2, Online Resource 3). Except for the *discussions about practice situations with the trainer*, LiFE participants evaluated all aspects in this category to be very helpful (*Mdn*=6). gLiFE participants perceived all aspects of the gLiFE knowledge transfer to be helpful (*Mdn*=5). The low IQR values (1 < IQR < 1,5) indicate

a high consensus between participants in both formats. In this category, differences between formats were not significant (shown in Table 2).

Comparison between formats: Category 3 "materials/contents" (T1)

Descriptive analyses showed equal medians in this category: teaching of *theoretical content* about behavior change, "*if-then" sentences* for planning the LiFE activities, *materials* for learning how to perform the activities correctly, *LiFE manual*, and *workbook* (see Table 2, Online Resource 3). However, there was the significant, "small to medium" difference that *helpfulness of the "if-then" sentences* was rated higher in LiFE (Mdn_{rank}=139.17) compared to gLiFE (Mdn_{rank}=112.72; U=6.216, p=.002, n=251; r=.19; shown in Table 2). IQRs showed larger distribution of responses in LiFE.

Comparison between formats: Category 4 "program outcomes" (T1)

For both formats, descriptive analysis showed an equal and rather high evaluation of participants' perceived *physical improvements* and *satisfaction with improvements in balance and strength* (see Table 2, Online Resource 3). However, IQRs were somewhat higher in gLiFE, indicating rather dispersed responses. *Overall satisfaction with program results* was rated highest in both groups. LiFE participants rated their *satisfaction with the improvement in physical activity* slightly but insignificantly higher than gLiFE participants (shown in Table 2).

Results from the 12-month follow-up (T2)

Descriptive overview (T2)

At T2 (shown in Table 2) few deviations were seen compared to the medians at T1. Median differences ranged from 0.5 to 1 in five items of the LiFE and three items of the gLiFE questionnaire. IQRs of 1 were found in 83% of all items in LiFE and in 80% of gLiFE, indicating a slightly greater agreement between participants compared to T1. The IQR value for the item *appraisal of the other* format was 3 in the LiFE format, indicating that LiFE participants did not fully share the same opinion on whether gLiFE would hypothetically have been helpful or not.

Comparison between formats (T2)

While evaluations regarding *overall rating*, *physical challenge*, *integrability into daily life*, and *satisfaction with improvement in physical activity* differed to some extent between formats at T1, T2 data showed equal medians in both formats (shown in Table 2). Most group differences remained constant and insignificant; there was only one significant "small to medium" difference indicating that LiFE participants (Mdn_{rank}=134.14) rated their *satisfaction with improvement in strength* significantly higher compared to gLiFE participants (Mdn_{rank}=106.86; U=5.563, p < .001, n=120; r=.21).

Differences within formats over time (T1/T2)

In LiFE, participants rated *integrability into daily life* significantly lower (Mdn_{T2}=3) at T2, indicating a “medium to large” difference within the LiFE group compared to the evaluation at T1 (Mdn_{T1}=4; z=-4.003, p < .001, n=120; r=.37; shown in Table 2). Another significant difference with a large effect size was found within LiFE regarding the higher scores for *helpfulness of discussing practice situations with the trainer* at T1 (Mdn_{T1}=5) compared to T2 (Mdn_{T2}=6; z=-9.006, p < .001, n=120; r=.82).

In gLiFE, the analysis showed lower medians at T2 compared to T1 regarding the *overall rating*, *integrability into daily life* and the *helpfulness of “if-then” sentences*. However, there were no significant differences between the evaluations at both measurement points in gLiFE.

Table 2: Results from the LiFE and gLiFE evaluation questionnaire, differences between formats (T1 and T2), differences within formats over time (T1/T2)

	6-month follow-up (T1)			12-month follow-up (T2)			
	Median (IQR)		group difference p-value□ (effect size†)	Median (IQR)		group difference p-value□ (effect size †)	T1/T2 difference p-value□□ (effect size †)
	LiFE	gLiFE		LiFE	gLiFE		LiFE / gLiFE
	N = 126	*N* = 126		*N* = 120	*N* = 120		LiFE / gLiFE
Category 1: "Overall evaluation"							
Overall rating[a]	5 (1)	5,5 (1)	.995	5 (1)	5 (1)	.917	.532 / .746
Safety practicing during the home visit[b]/ the group session[b]	6 (1)	5 (1)	-	6 (1)	5 (1)	-	.187 / .279
Safety practicing alone at home[b]	5 (1)	5 (1)	.01	5 (1)	5 (1)	.059	.601 / .473
Physical challenge[c]	3 (2)	4 (1)	.313	4 (1)	4 (1)	.325	.762 / .972
Integrability into daily life[d]	4 (2)	4 (1)	.011	3 (1)	3 (1)	.589	**< .001 (.37)** / .060
Appraisal of the other format[e]	3 (2)	4 (2)	-	3 (3)	4 (2)	-	.016 / .171
Category 2: "Knowledge transfer"							
Exchange with trainer[e]/with group[e]	6 (1)	5 (1)	-	6 (1)	5 (1)	-	.007 / .413
Repetition of activities at home[e]/during group session[e]	6 (1)	5 (1)	-	6 (1)	5 (1)	-	.869 / .019
Discuss practice situations with trainer[e]/other participants[e]	5 (1)	5 (1)	-	6 (1)	5 (1)	-	**< .001 (.82)** / .439
Practice in the situation with trainer at home[e]/ with people in your age in a group[e]	6 (1)	5 (1,5)	-	6 (1)	5 (0,5)	-	.128 / .913
Writing down possible practice siutation on posters[e]	-	5 (1,5)	-	-	5 (1)	-	- / .357
Visualize practice situations in the group[e]	-	5 (1)	-	-	5 (1)	-	- / .435

Category 3: "Materials/contents"								
Theoretical content about LiFE[e]	5 (1)	5 (1)	.97	5 (1)	5 (1)	.322	.238	.066
"If-then" sentences for planning LiFE activities[e]	5 (1)	5 (1)	**.002 (.19)**	5 (1)	4 (1)	.009	.083	.876
Materials to perform activities correctly[e]	5 (2)	5 (1)	-	5 (2)	5 (1)	-	.668	.248
Participant's LiFE manual[e]	5 (1)	5 (1)	.415	5 (1)	5 (1)	.681	.966	.690
Participant's LiFE workbook[e]	5 (2)	5 (1)	.01	5 (2)	5 (1)	.007	.736	.450
Category 4: "Program outcomes"								
Improvement in balance[f]	4 (2)	4 (2)	.71	4 (1)	4 (2)	.154	.257	.764
Improvement in strength[f]	4 (1)	4 (2)	.319	4 (2)	4 (2)	.566	.018	.212
Improvement in PA[f]	4 (1)	4 (2)	.006	4 (1)	4 (1)	.032	.327	.930
Principles "move more" and "sit less" helped increase PA[f]	4,5 (1)	4 (1)	.278	5 (1)	4 (1)	.656	.979	.148
Overall satisfaction with results[g]	5 (1)	5 (1)	.226	5 (1)	5 (1)	.152	.343	.351
Satisfaction Improvement in balance[g]	4 (1)	4 (2)	.139	4 (1)	4 (2)	.054	.538	.758
Satisfaction Improvement in strength[g]	4 (1)	4 (1)	.158	4 (1)	4 (1)	**.001 (.21)**	.712	.010
Satisfaction Improvement in PA[g]	5 (1)	4 (1)	.185	4 (1)	4 (1)	.109	.996	.730

[a]scale "1= poor, 6 = very good", [b]scale "1=very unsafe, 6 = very safe", [c]scale "1 = very easy, 6 = very challenging", [d]scale "1 = very difficult, 6 = very easy", [e]scale "1= not helpful at all, 6= very helpful", [f]scale "1= not at all, 6 = very much", [g]scale "1 = very unsatisfied, 6 = very satisfied), PA = physical activity

level of significance for group differences $p < .003$,

level of significance for differences within formats T1/T2 $p < .002$,

[†]Pearson's "*r*" was calculated for significant results, indicates the effect size of the difference between formats/between T1 and T2

Discussion/Conclusion

This is the first study to examine participants' perception of the individual and group-based LiFE format. Since participants' acceptability is assumed to influence intervention effectiveness [24], our findings are an important part of the evaluation of the LiFE-is-LiFE trial [13]. Overall, participants evaluated both formats positively, reflecting the findings from the focus group interviews on acceptability in a small subsample [15]. There is consensus between LiFE and gLiFE participants, confirming that the subgoal of the LiFE-is-LiFE trial, to develop a group format which is less resource-intensive but equally effective also from the clinical point of view, was achieved. The largely consistent results across both follow-ups suggest a high level of participants' acceptance, which is essential for long-term and effective integrability [25]. Furthermore, the present study revealed important insights into the participants' perspective with respect to general and program-specific potentials and strategies for optimization helpful to further improve LiFE and gLiFE. In the following, we will interpret both results from descriptive and inferential statistics in each category.

Overall evaluation

Both LiFE and gLiFE participants were satisfied with the LiFE approach in general, supporting already existing evidence on the acceptability of lifestyle-integrated training [26]. Equal overall ratings of both formats at T2 underline the acceptability also in the long term [11, 15]. The fact that gLiFE participants did not feel as safe as LiFE participants during the intervention sessions is in line with the results of a recent analysis [27] and could be caused by the lower trainer-participant ratio and less supervision during gLiFE sessions. However, gLiFE participants felt equally safe as LiFE participants practicing at home, which indicates that gLiFE trainers have instructed participants well on how to train safely at home, even though they had not seen the individual home environment.

Participants perceived the LiFE activities as challenging, although the training intensity might have been too low to induce functional improvements [13]. This could have been caused by a mismatch between subjective and objective intensity levels. Another explanation might be that participants did not appropriately adapt the difficulty of the LiFE activities to their training progress during and after the intervention period. To achieve functional improvements, trainers should therefore give a higher priority on teaching participants how to challenge themselves regarding their limits of physical capability and how to continue to upgrade the LiFE activities depending on their own training progress. The participants evaluated the integrability of activities in LiFE and gLiFE lower over time. In LiFE, this longitudinal effect was significant with a moderate to large effect size. In a focus group study [15], LiFE participants mentioned having difficulties with the transition from being directly supervised by a trainer to practicing alone at home. Furthermore, just as in previous studies [10, 15], participants might have perceived

activities as easy to integrate (e.g., one leg stand) and others as more difficult (e.g. stepping over objects backwards). A detailed analysis of the LiFE activities revealed that participants had favorite (such as “tandem walk”) and less preferred (such as “move leg sideways walking”) balance and strength activities [27].

However, the present results leave it open whether or to what extent the actual adherence of performing the LiFE activities decreased in both formats. At this point, other studies provide objective and promising results: Frequency of the performed LiFE activities was almost equal, as shown in a recent analysis of the LiFE-is-LiFE data (LiFE activities out of 16/week; LiFE: 11.18, gLiFE: 11.20) [27]. A slightly younger sample ($mean_{age}$ = 66.4 years) [10] implemented 12 out of 16 activities ($mean_{\text{adherence}}$ = 76%) within four weeks. In the randomized controlled LiFE trial by Clemson and colleagues [8] adherence was significantly higher in the LiFE program with 64% of the participants exercising at twelve months compared to 35% in the structured exercise program. In a pilot study [11], most of the gLiFE participants had implemented around 75% of the LiFE activities over a 7-week intervention period. Nevertheless, to support long-term execution it might be useful to consider additional trainer support, for example a refresher phone call, workshop, or home-visit after twelve months.

Knowledge transfer

The descriptive data show highest possible evaluation scores for the one-to-one delivery format. In the long term, all LiFE-characteristic aspects were rated slightly but insignificantly more positively compared to gLiFE. A stronger participant-trainer relationship in LiFE could explain these results that are reinforced by findings from the focus group study [15] where LiFE participants explained that they appreciated the direct personal exchange with the trainer, the individual adaption of activities, and the feedback during the one-to-one supervision. In the present study, gLiFE participants found it helpful to practice with people of the same age in a group. Although the differences between formats were not significant, the results suggest that the individual trainer support could be more beneficial than the presence of peers for older adults. The effects of LiFE and gLiFE on the psychological determinants of behavior change suggest that LiFE participants experienced significantly higher levels of relatedness than gLiFE participants [28].

LiFE participants rated the helpfulness of discussing activities with a trainer significantly higher at T2 compared to T1, with a large effect size. Considering that gLiFE participants rated the group discussion to be helpful, but not very helpful, and that gLiFE participants liked the idea of learning LiFE activities at home more than vice versa, stronger integration of individual supervision could be implemented when refining gLiFE. Perhaps, offering short one-to-one time slots during the two-trainer-group-sessions would already be a program improvement for participants and not necessarily more resource-intensive. Of course, it would then have to be

ensured that the safety of the group would not be compromised. Another, much more elaborate possibility would be to integrate a single home visit into the gLiFE program, as it has already been suggested by gLiFE focus group participants [15]. Gibbs et al. [29] formulated a similar recommendation for implementing their adapted group-based “Mi-LiFE” program in primary care.

Materials/contents

Results show that the modified and newly developed materials and contents were well received. The significantly better rating of the “if-then” plans in LiFE at T1 could be due to the closer supervision when creating those plans. LiFE participants might have formulated more precise and feasible plans, which were then perceived as more helpful when practicing LiFE. In the focus group interview, some gLiFE participants reported that the plans they created during the sessions were not feasible at home [15].

Program outcomes

LiFE and gLiFE participants rated their perceived improvements in balance, strength, and physical activity and their satisfaction with those improvements positively, indicating that the delivery format might not have a large impact on the perceived effectiveness of the LiFE activities. Participants’ satisfaction with their increases in physical activity are in line with improvements in steps per day in both formats (LiFE +386, gLiFE + 1.266) [13] but do not reflect the significantly higher increase of steps per day in gLiFE compared to LiFE. The only significant difference was that LiFE participants were more satisfied with their improvement in strength than gLiFE participants after twelve months. Hence, it seems that subjective evaluation is not in line with directly measured results.

The physical activity principles “move more” and “sit less” were perceived as more helpful for increasing perceived physical activity in LiFE compared to gLiFE at both measurement points. Although not significant, this difference could again be due to the decreased levels of integrability in LiFE participants. LiFE participants may benefit from a higher focus on specific implementation strategies, such as the LiFE principles.

Methodological considerations

One limitation of the present study is the susceptibility of self-reports to recall and response bias [30]. Behaviors that occur frequently are unlikely to be specifically present in memory in the long term [31], which might have biased self-reported integrability of LiFE activities in the present results at both follow-ups. Furthermore, participants in both formats may have rated the helpfulness of the other program lower to avoid indirect criticism of their own attended program. A noteworthy strength of the present study lies in the large, consecutively recruited

sample of the LiFE-is-LiFE trial, which provides a reliable basis for representative, generalizable results and implications for future research and implementation projects.

Implications

The need for rapid and effective measures to improve older adults' health care is growing continuously in the face of population aging [32]. In order to achieve that, evidence-based interventions such as the LiFE and gLiFE program should be translated into practice [33]. The present study further confirms the acceptance of LiFE and gLiFE. For this reason, future studies should strive to translate LiFE and gLiFE into practice to utilize the knowledge from the LiFE studies carried out in the last years [34] and to reach a large-scale availability for the target group. An important part of further implementation studies should be the examination of the proposed adaptations regarding individual supervision in gLiFE as well as analyses of LiFE's and gLiFE's long-term integrability, feasibility, and effectiveness.

Conclusion

In summary, both programs were mostly equally and well-received by participants which is consistent with findings from previous research on LiFE [8, 15] and the recently developed gLiFE program [11, 15]. With a few exceptions, the differences between formats were not significant and results within the formats remained stable over time regarding the overall evaluation, program outcomes, knowledge transfer, and content and materials of LiFE and gLiFE. The present findings allow the derivation of program refinements such as additional strategies focusing on LiFE's long-term maintenance and a stronger integration of individual supervision in gLiFE. These optimizations should be considered for future implementation studies to make LiFE and gLiFE available for older adults with best-possible participant satisfaction, safety, and outcome success. The results from the participants' evaluation reinforce findings from the LiFE-is-LiFE trial that the recently developed gLiFE program is a promising and comparable alternative to the individual LiFE program.

Statements and Declarations

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Compliance with ethical standards

Ethical approval was obtained for both sites: Heidelberg document number Schwe2017 2/1–1; Stuttgart document number 723/2017BO2. All participants gave written informed consent prior to participation. The study is conforming to the respective policy and mandates of the Declaration of Helsinki.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

All authors contributed to the study conception and design. Development of the grand proposal for the LiFE-is-LiFE trial [Michael Schwenk, Clemens Becker], coordination and conduct of the LiFE-is-LiFE study [Carl-Philipp Jansen, Corinna Nerz, Sarah Labudek], data analysis and interpretation [Melissa J. Wolf, Sarah Labudek, Carl-Philipp Jansen], draft of manuscript [Melissa J. Wolf, Sarah Labudek, Carl-Philipp Jansen, Christoph Endress], all authors commented on previous versions of the manuscript. All authors have read and approved the final manuscript.

Data Availability Statement

The data used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Publication VI

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Research Article

Changes in psychological determinants of behavior change after individual vs. group-based lifestyle-integrated fall prevention: Results from the LiFE-is-LiFE trial

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Short Title: Changes in psychological determinants of behavior change through (g)LiFE

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Abstract

Objective: The Lifestyle-integrated Functional Exercise (LiFE) intervention has shown to promote physical activity in fall-prone older adults. However, the underlying mechanisms of how LiFE remain unclear. This study compares the effects of the individual and group-based LiFE format on psychological determinants of behavior change derived from the health action process approach, habit formation theory, and self-determination theory.

Methods: Secondary analysis on basis of the randomized, non-inferiority LiFE-is-LiFE trial were performed. Questionnaire data on psychological determinants were obtained from older adults (*M* = 78.8 years, range 70–95) who took part in either the individual (*n* = 156) or the group-based (*n* = 153) LiFE intervention. Measurement points varied from three to six times, and from baseline (T1) up to a 12-month follow-up (T6). A generalized linear mixed model was specified for each determinant.

Results: Both LiFE and gLiFE participants reported lower levels of motivational determinants at T6. LiFE participants showed significantly higher values of action planning and coping planning at T6. Participants in both formats showed increased levels of action control at T6, whereas participants' habit strength decreased post-intervention, but then stabilized over time. LiFE participants showed higher levels of autonomy, competence, and relatedness throughout the study, but levels of intrinsic motivation did not differ between formats and from T1 to T6.

Conclusion: In both formats, but especially in the individual LiFE, the Behavior Change Techniques (BCTs) used affected volitional rather than motivational or general determinants of behavior change. Habit strength as an important indicator of the sustainability of the LiFE exercises stabilized over time, indicating that participants, at least partly, sustained their formed habits long-term.

Introduction

Our aging society is in high need for effective health promotion of older adults. Physical activity as a health-promoting behavior has shown positive effects on morbidity, quality of life, independence, and well-being in older age [1–4]. In Europe, however, only 23,6% of older men and 17,4% of older women meet the WHO recommendations [5] of 150 minutes of moderate to vigorous physical activity per week and muscle strengthening activities twice a week [6]. Especially for older adults with low physical function, higher levels of physical activity are associated with a higher risk exposure for falls [7,8]. Therefore, more recent recommendations foresee multi-component physical activity including aerobic, balance, and muscle-strengthening exercises for older adults [9] which have been found to be effective in reducing falls [10].

Lifestyle-integrated Functional Exercise

The Lifestyle-integrated Functional Exercise (LiFE) intervention is a multicomponent intervention aiming to improve physical activity safely by integrating functional balance and strength activities into older adults' daily routines [11]. In a randomized controlled trial, LiFE has shown to reduce falls rate by 31% compared to a sham intervention group [11]. Additionally, LiFE participants showed better adherence rates than participants who received structured training (i.e., five intervention sessions and two booster phone calls, training should be performed independently three times per week) in this study, indicating that the mechanisms underlying LiFE might be different from structured training. However, the psychological mechanisms in LiFE which might induce behavioral changes and thereby lead to adherence and long-term behavior change have not been investigated yet.

Theoretical foundation of the behavior change concept in (g)LiFE

A theoretical concept on behavior change through LiFE already existed [12], but was refined in the development process of gLiFE. Three behavior change theories, the health action process approach (HAPA), habit formation theory, and the self-determination theory were used to describe the behavior change process which is assumed to be initiated through participating in LiFE and gLiFE. The HAPA [13] assumes that individuals first form an

intention to change their health behavior, by altered levels of self-efficacy, outcome expectancies, and risk perception. Thereafter, volitional strategies such as action planning, coping planning, and action control help to translate and realize the set intention. To make behavioral changes last, habit formation theory [14] presumes that through context-dependent repetition of a certain health behavior (i.e., squatting every time when reaching for the lower shelf in the kitchen), an association between the context and the behavior forms which automatically elicits an impulse for behavioral enactment when entering the context with time. Habit strength is defined as the degree to which behavioral enactment is assumed to be driven by the underlying context-behavior association. Once established, habits are assumed to be persistent against motivational or behavioral lapses and thereby ensure maintenance of behavioral change [15]. Complementary, the self-determination theory [16,17] proposes that through establishing a sense of autonomy, competence, and relatedness, intrinsic motivation arises and promotes long-term maintenance of health behaviors.

Active Ingredients of behavioral interventions: behavior change techniques

To date, behavioral interventions such as LiFE are criticized for being “black boxes” that offer little insight into the psychological mechanisms of behavior change [18]. As depicted in Figure 1, theory behind the functioning of behavior change interventions assumes that interventions first affect psychological determinants of behavior change before leading to behavioral changes or improvements in physical health outcomes. In the last decade, extensive scientific efforts have been taken to standardize the design and reporting of the content of behavioral interventions (e.g., the TiDIER checklist; [19]), with the most applied model being the behavior change technique (BCT) taxonomy v1 [20]. BCT is defined as the “observable, replicable and irreducible component of an intervention designed to alter or redirect causal processes that regulate behavior“ [21]. Although more and more intervention studies comprise lists of implemented BCTs [19], publications often lack a rationale for the theoretical derivation of those BCTs or make assumptions about their effect on the target

behavior [22]. Interventions which include a set of BCTs aligned with a behavior change theory have been linked to higher intervention effectiveness [23].

The active ingredients of LiFE and gLiFE

So far, the BCTs for the original, individual LiFE format have not been delineated. The BCTs of LiFE were coded in the process of developing the group-based LiFE (gLiFE) format (Kramer, Labudek et al., 2020). Furthermore, each BCT was linked to its theory-based predictor of behavior change. Motivational (e.g., “goal setting (behavior)”, BCT number 1.1.) and volitional (“action planning”, BCT number 1.4.) BCTs were linked to the health action process approach (HAPA; Schwarzer, 2008) and BCTs which explicitly address habit formation (“prompts/cues”, BCT number 7.1.) were linked to the theory on habit formation [14]. On a more general level, LiFE is also assumed to promote autonomy, competence, relatedness, and intrinsic motivation: constructs derived from the self-determination theory [17] in participants.

Aim of the study

This study presents secondary analyses on effects of the LiFE-is-LiFE trial [25]. The trial compared the individual LiFE format to the newly developed group-based (gLiFE) format regarding falls, physical activity, and intervention costs. The results are published elsewhere [26].

In this study, we examined the differential effects of the two LiFE formats on sets of theory-based, psychological determinants of behavior change, i.e., motivational and volitional determinants, habit strength, and more general psychological determinants such as autonomy, competence, relatedness, and intrinsic motivation.

So far, the changes in psychological determinants have never been explicitly examined in LiFE. We expected similar effects because gLiFE was designed on basis of LiFE [24]. We hypothesized gLiFE and LiFE to induce similar effects on a) motivational determinants, i.e., self-efficacy, outcome expectancies, and intention; b) volitional determinants, i.e., action planning, coping planning, and action control; c) habit strength; d) general psychosocial determinants, i.e., autonomy and competence. We further expected gLiFE and LiFE not to

induce changes in HAPA-based risk perception, because risk perception was no explicit part of the intervention content. Relatedness is expected to be better promoted by gLiFE through the presence of peers. The examination of changes in psychological determinants of behavior change in both LiFE and gLiFE might reveal whether the altered mode of delivery and the extended education on behavior change theory in gLiFE led to differential effects.

Methods

This study presents secondary analysis on basis of the of the LiFE-is-LiFE trial, a pre-registered (clinicaltrials.gov; identifier: NCT03462654) multi-center, single-blinded, randomized non-inferiority trial which was conducted between June 2018 and August 2020 in Stuttgart and Heidelberg, Germany . Ethics approval was obtained by both local ethics committees. The study protocol [25]provides comprehensive information on the full trial. In this paper, only the information relevant to the research question and analysis will be listed.

Participants and procedure

Older adults were eligible for study participation if they were community-dwelling, aged 70 years and older, had experienced either one injurious fall, more than one non-injurious fall in the past year, or if they were at risk of falling. Risk of falling was determined by participants' subjective experience of balance decline and a completion time of ≥ 12 seconds for the "Timed-Up-and-Go" test [27]. Participants were excluded in case of severe medical conditions or cognitive impairment (Montreal Cognitive Assessment < 23; [28]) or if they engaged in more than 150 minutes of at least moderate physical activity per week already. Potential participants were contacted by municipal registration offices in two cities in Germany. Interested persons underwent a two-step screening procedure, i.e., pre-screening via telephone and further screening at the study center. If eligible, participants signed informed consent and underwent a baseline assessment (T1) including psychosocial questionnaires supported by trained assessors. Participants were then randomized into one of the two intervention arms, either the LiFE (n = 156) or the gLiFE format (n = 153). The full participant flow is provided in supplementary file 1. Some of the core determinants were assessed at the last intervention session (T2). Participants also received two booster phone

calls four (T3) and ten weeks (T4) after the last intervention session, which also contained an assessment of the core determinants. Follow-up assessments took place 6 months (T5) and 12 months (T6) after the first intervention session with a tolerance of ± 2 weeks. At T6, data from *n* = 123 LiFE and *n* = 122 gLiFE participants were available (79.32%). Due to the onset of the Covid 19 pandemic, the T6 measurement was delayed in *n* = 37 participants.

Intervention and BCTs

LiFE contains 16 activities to increase balance, lower limb strength, and overall physical activity. It requires participants to understand and apply the LiFE training principles such as “reduce the base of support” for balance training or “load your muscles” for strength training. From a behavior change perspective, LiFE fosters the creation of new habits by integrating the LiFE activities into everyday activities and aims to encourage participants to manage their training individually beyond the intervention period.

Regarding the delivery, both LiFE formats were carried out in seven intervention sessions over the course of 11 weeks, followed-up by two booster phone calls by trained instructors. LiFE sessions lasted approximately 1-1.5 hours whereas gLiFE sessions lasted approximately 2 hours. gLiFE sessions took place at the study centers or municipal centers close to participants’ living areas. gLiFE was delivered to a group of 8-12 participants by two trainers. In both formats, participants received the LiFE participants’ manual and a workbook in which they could document their implementation intentions and self-monitor their LiFE training. The largest difference between formats was that LiFE participants could try and practice the LiFE activities in their own home environment together with the trainer. gLiFE participants, however, practiced the correct movement execution of the LiFE activities in a group setting and then visualized themselves performing the LiFE activities at home.

LiFE already contained a large focus on long-term behavior change through habit formation (Clemson & Munro, 2015), and the BCTs of an adapted version of the LiFE format for young seniors have been identified in a previous study [29]. While developing the gLiFE concept (Kramer, Labudek et al., 2020), the theoretical basis was expanded by the HAPA [13], habit formation theory [14], and self-determination theory [17]. For example, participants

used action planning (BCT 1.4.) in the shape of implementation intentions [30] to link a specific LiFE activity, such as squatting, to a certain daily activity such as reaching for the lower shelf of the kitchen cabinet. A list of all BCTs coded after the BCT taxonomy v1 [21], the related construct and related health behavior change theory and their form of delivery is provided in Table 1. In comparison to the list of BCTs provided in the concept paper of gLiFE (Kramer, Labudek et al., 2020), this table contains additional BCTs which were not explicitly linked to the group setting (e.g., 8.3. habit formation). Furthermore, the recently developed classification for motivation and behavior change techniques (MBCTs) used in self-determination theory-based interventions [31] was added if applicable. In total, LiFE contains 21 BCTs and gLiFE contains 22 BCTs, the added BCT being “mental rehearsal of successful performance” (15.2.). The most frequent categories of BCTs are “goals and planning” (1.), “feedback and monitoring (2.), and “repetition and substitutions” (8.).

Measures

HAPA items were acquired from other studies [13,32] and adapted to the LiFE context. Items were assessed via a 6-point Likert-scale ranging from *not true at all* (1) to *totally true* (6), except for *risk perception*, which was measured on a scale ranging from *much below average* (1) to *much above average* (5). All assessed HAPA determinants, their internal consistencies (Cronbach’s alpha), and exemplary items are listed in Table 2. Self-efficacy, outcome expectancies, and risk perception regarding falls and loss of functional decline was assessed at three measurement points. Intention, action planning, coping planning, and action control were assessed at all six measurement points. *Habit strength* was assessed via the German version [33] of the Self-Regulation Behavioral Automaticity Index (SRBAI; Gardner, Abraham, et al., 2012). This contains four items which are assessed on a 7-point Likert-scale ranging from *totally disagree (1)* to *totally agree (7)*. Habit strength was assessed at five measurement points. The word ‘exercise’ was replaced by ‘being physically active’, e.g., “I am physically active because it’s fun”. Perceived autonomy, competence, and relatedness were assessed using the German psychological need satisfaction in exercise scale (Rackow et al., 2013) at the beginning (session 2) and the end

of the intervention (last intervention session) on a 7-point Likert Scale ranging from *totally disagree (1)* to *totally agree (7)*. The wording “training program” was substituted by “the LiFE program”. Full scales were used for assessing autonomy (3 items) and competence (4 items). Relatedness was assessed using the item “I feel connected to the people I interact with in the LiFE program”. *Intrinsic motivation* was assessed at baseline (T1), 6-month (T5) and 12-month (T6) follow-ups using four items on a scale from *not true for me (0)* to v*ery true for me (4)* of the German version [36] of the Behavioral Regulation in Exercise Questionnaire (BRE-Q 3).

Demographic data

Regarding demographic variables, participants’ age, gender, height (cm), weight (kg), cognitive status (Montreal Cognitive Assessment; Nasreddine et al., 2005), percentage of fallers in the past six months, concerns about falling (Short Falls-Efficacy Scale International; Kempen et al., 2008) education level (years of education), highest degree of education, and marital status were assessed at baseline.

Data analysis

Bivariate associations between psychological determinants of behavior change were examined using Pearson’s correlation coefficient. To examine the change of psychological determinants over time and to account for within-person change over time, linear mixed models (LMM) were applied in R version 4.0.3. [38] using the lme4 package. R scripts containing the main analyses are available on https://osf.io/4rxqt/?view_only=f9ee63d9aba9464fa4d93779fa685abf. In comparison to a repeated measures ANOVA, LMM facilitates better handling of missing data and functions with fewer assumptions. Data from participants who attended at least one intervention session (n = 294) was included in the analyses. In all models, the respective determinant was specified as the outcome, whereas time (effect-coded), intervention format (LiFE/gLiFE; effect-coded) as well as the interaction between time and intervention format were specified as predictors. Time was used as a factor variable with 3 to a maximum of 6 values, depending on the amount of available measurement points per participants. Effect coding of

both factors (time and intervention format) was applied for a better interpretation of main and interaction effects, with gLiFE and the last measurement point serving as the contrasting intervention format. Maximum likelihood estimation was used to estimate coefficients and all models were specified with random intercepts, i.e., the intercepts were allowed to vary between participants. Models containing random slopes for time, which would have depicted the individual change of levels of psychological determinants over time, could not be identified due to a lack of power. On basis of the LMMs, an ANOVA was specified using the car package to examine omnibus main and interaction effects. Post-hoc comparisons were performed using the emmeans package and adjusted for multiple testing using Tukey's HSD. For sensitivity analyses, we calculated the analyses on basis of a) a high attendance sample (n_{LiFE} = 117, n_{gLiFE} = 46), i.e., participants who attended all nine intervention sessions to examine whether participants who receive a “high dosage” of the LiFE and gLiFE intervention show differential patterns of changes in psychological determinants and b) a sample comprised of participants whose 12-month follow up was *not* delayed due to the Covid-19 pandemic (n_{LiFE} = 128, n_{gLiFE} = 129).

Results

Sample characteristics

The total sample of N = 294 older adults which were included in the analyses was comprised of n = 148 LiFE and n = 146 gLiFE participants. Sample characteristics are displayed in Table 3. No significant differences in age, gender distribution, BMI, cognitive status, number of fallers, concerns about falling, and years of education between intervention formats could be identified by an independent samples t-test. Dropout analyses revealed that individuals who dropped out before the first intervention session (n = 15) reported significantly lower levels of coping planning, $t(16.7) = -2.85$, $p = .011$, and action control, $t(17.4) = -2.22$, $p = .040$, than the n = 294 participants who were included in the analyses.

Changes in psychological determinants of behavior change

Correlation tables providing baseline and follow-up values of all psychological determinants of behavior change are provided in supplementary file 2. On a general level,

most correlations were small to medium, with only few being > .50. Both LiFE and gLiFE participants showed a higher number of significant correlations at follow-up than at baseline, with gLiFE participants showing a higher pre-post intervention difference in the number of significant correlations.

In the following, the results of the linear mixed models will be presented. Figure 2 depicts means and standard errors of all measured psychological determinants of behavior change from baseline to 12-month follow-up by LiFE and gLiFE. Of the three potential significant effects (time, group, time x group interaction), only the significant results will be reported in the text.

Intervention Effects on Exercise-specific, Motivational Determinants: Self-efficacy, Outcome Expectancies, Risk Perception, and Intention

For *self-efficacy*, results showed a significant effect of time ($F(2,528) = 21.76$, $p < .001$, $\eta_p^2 = 0.08$). Post-hoc comparisons revealed, compared to baseline, levels of self-efficacy were significantly lower at 12-month follow-up (T6) in both LiFE ($b = -0.23$, $p = .006$) and gLiFE ($b = -0.37$, $p < .001$). For *outcome expectancies*, results showed a significant effect of time ($F(2,529) = 3.78$, $p = .024$, $\eta_p^2 = 0.01$). Compared to the baseline, levels of outcome expectancies were significantly lower at the 12-month follow up (T6) in gLiFE ($b = -0.29$, $p = .021$), but not in LiFE ($b = 0.07$, $p = .979$). For *risk perception* regarding falls and loss of functional decline, results showed a significant effect of time ($F(2,529) = 17.91$, $p < .001$, $\eta_p^2 = 0.06$). Compared to the baseline, both LiFE ($b = -0.28$, $p < .001$) and gLiFE ($b = -0.19$, $p = .019$) showed significantly lower levels of risk perception at 12-month follow up (T6). For *intention*, there was a significant effect of time and intervention format, i.e., levels of intention differed significantly over time ($F(5,1317) = 236.36$, $p < .001$, $\eta_p^2 = 0.48$) and between the two intervention formats ($F(1,281) = 7.53$, $p = .006$, $\eta_p^2 = 0.03$). Although post-hoc analyses revealed some significant changes over time, for example a significant decrease from T2 to T3 ($b = -0.48$, $p < .001$) or a significant increase from T4 to T5 ($b = 2.27$, $p < .001$), there was no difference in levels of intention between both LiFE ($b = -0.15$, $p = .973$) and gLiFE ($b = -0.29$, $p = .312$) at 12-month follow-up (T6) compared to baseline.

Sensitivity analyses with the high attendance sample revealed no changes in the effects on self-efficacy and risk perception. For outcome expectancies, the negative effect of time diminished, as participants who attended all nine intervention sessions reported stable levels of outcome expectancies over time. For intention, the effect for intervention format diminished, as highly attendant participants in both formats showed similar levels of intention over time. Sensitivity analyses for the sample measured in time at the 12-month follow up revealed no differences in self-efficacy and outcome expectancies. For risk perception, results differed in a sense that the effect of time was still significant, although only LiFE showed significantly lower levels of risk perception at 12-month follow-up (T6) compared to the baseline (T1). For intention, the group effect diminished, as LiFE and gLiFE participants who got measures in time at 12-month follow-up did not differ in their levels of intention.

Intervention Effects on Exercise-specific Volitional Determinants: Action Planning, Coping Planning, and Action Control

For *action planning*, both the main effect of time ($F(5,1312) = 63.65$, $p < .001$, $\eta_p^2 = 0.20$) and the interaction effect of time and intervention format ($F(5,1312) = 2.35$, $p = .039$, $\eta_p^2 = 0.01$) were significant. Post-hoc comparisons revealed that although levels of action planning changed significantly between time points in both groups, e.g. increased significantly from T1 to T2 in both LiFE ($b = 1.95$, $p < .001$) and gLiFE ($b = 1.75$, $p < .001$), only LiFE showed significantly higher values of action planning at T6 ($b = 0.80$, $p < .001$).

For *coping planning*, results also revealed a significant main effect of time ($F(5,1312) = 54.26$, $p < .001$, $\eta_p^2 = 0.17$) and a significant interaction effect of time and intervention format ($F(5,1312) = 2.24$, $p = .048$, $\eta_p^2 = 0.01$). Similar to action planning, post-hoc tests revealed that levels of coping planning changed significantly over time between groups, e.g., increased from T1 to T2 in both LiFE ($b = 1.50$, $p < .001$) and gLiFE ($b = 1.38$, $p < .001$). Again, LiFE ($b = 0.63$, $p = .012$) but not gLiFE ($b = 0.41$, $p = .393$) showed significantly higher values of coping planning at T6 compared to the baseline.

For *action control*, the results showed significant effects for time ($F(5,1308) = 54.93$, $p < .001$, $\eta_p^2 = 0.17$), intervention format ($F(1,285) = 4.19$, $p = .042$, $\eta_p^2 = 0.01$), and the

interaction between time and intervention format ($F(5,1308) = 6.51$, $p < .001$, $\eta_p^2 = 0.02$). Post-hoc comparisons again revealed significant changes over time and between groups, e.g., a significant increase of action control from T3 to T4 in gLiFE ($b = 1.29$, $p < .001$) and a significant increase of action control in LiFE from T4 to T5 ($b = -0.61$, $p = .013$). Compared to the baseline (T1), LiFE ($b = 0.89$, $p < .001$) and gLiFE ($b = 0.64$, $p = .006$) showed significantly higher levels of action control at 12-month follow-up (T6), with no significant difference between LiFE and gLiFE.

Sensitivity analyses revealed that the interaction effect of time and intervention format diminished, with highly attendant LiFE participants no longer showing higher levels of action and coping planning when compared to gLiFE participants at the 12-month follow-up. For action control, the significant effect of the intervention format diminished, as highly attendant LiFE and gLiFE participants showed similar levels of action planning over time with significantly higher levels at T6 compared to the baseline (LiFE [$b = 0.72$, $p = .011$], gLiFE [$b = 1.09$, $p = .019$]). For the sample measured in time at the 12-month follow up, we found no differences in the effects for action planning, coping planning, and action control.

Intervention Effects on Behavioral Automaticity: Habit Strength

For *habit strength*, which was first assessed at T2, results revealed a significant effect of time ($F(4,1017) = 30.95$, $p < .001$, $\eta_p^2 = 0.11$). Post-hoc comparisons revealed a significant decrease of habit strength from T2 to T3 for both LiFE ($b = -0.48$, $p = .004$) and gLiFE ($b = -0.50$, $p = .003$). From T3 to T6, there were no significant differences between points of measurement or intervention formats. Sensitivity analyses for the high attendance sample and for the sample measured in time at the 12-month follow up revealed no differences in the effects on habit strength (Figure 2).

Intervention Effects on General, Behavioral Determinants: Autonomy, Competence, Relatedness, and Intrinsic Motivation

For *autonomy*, results showed a significant effect for intervention format ($F(1,280) = 19.44$, $p < .001$, $\eta_p^2 = 0.07$). LiFE showed significantly higher values of autonomy than gLiFE at intervention session 2 ($b = 0.52$, $p < .001$) and at the last intervention session,

LiFE participants still reported higher values of autonomy than gLiFE participants (b = 0.43, p = .004). For *competence*, results showed – similar to autonomy – a significant effect for intervention format (F(1,280) = 21.42, p < .001, η_p^2 = 0.07). That is, LiFE participants showed significantly higher values of competence than gLiFE participants at intervention session 2 (b = 0.46, p < .001). At the last intervention session, LiFE participants still reported higher values of competence than gLiFE participants did (b = 0.40, p = .001). For *relatedness*, results showed a significant effect for time (F(1,267) = 16.31, p < .001, η_p^2 = 0.06) and intervention format (F(1,278) = 114.65, p < .001, η_p^2 = 0.30). LiFE participants already showed significantly higher values of relatedness than gLiFE participants at intervention session 2 (b = 1.40, p < .001). Levels of relatedness decreased over the course of the intervention sessions in both intervention formats, with the changes only being significant for gLiFE (b = -0.42, p = .011). At the last intervention session, LiFE participants still reported higher values of relatedness than gLiFE participants (b = 1.50, p < .001). For *intrinsic motivation*, the results showed a significant effect of time (F(2,520) = 7.19, p < .001, η_p^2 = 0.03). Specifically, intrinsic motivation increased from baseline (T1) to 6-month follow-up (T5), followed by a decrease from 6-month follow-up (T5) to 12-month follow-up (T6) in both LiFE and gLiFE, although the single changes were not statistically significant. Sensitivity analyses revealed no differences in the effects on intrinsic motivation, autonomy, competence, and relatedness for both the high attendance and the “12-month follow-up in-time” sample.

Discussion

This study examined potentially relevant theory-based, psychological determinants which might mediate the behavior change process in LiFE and gLiFE as two formats of a theory-based exercise intervention for fall-prone older adults. Our hypothesis that LiFE and gLiFE would similarly induce positive changes in self-efficacy, outcome expectancies, intention, action planning, coping planning, action control, habit strength, autonomy, competence, and intrinsic motivation was not fully confirmed. Likewise, gLiFE participants showed – contrary to our expectations – lower levels of relatedness post intervention. In both

formats, but especially in the individual LiFE, the BCTs used affected volitional rather than motivational or general determinants of behavior change. Thus, LiFE and gLiFE seem to effectively increase volitional skills such as action planning, coping planning, and action control in participants.

Self-efficacy, outcome expectancies, and risk perception are rarely assessed as predictors of intention at follow-up. Our analyses revealed that all three determinants showed lower values at follow-up for both formats. Lower levels of self-efficacy at 12-month follow-up compared to baseline might have resulted from participants' difficulty in implementation and long-term maintenance of the LiFE activities. It is possible that participants felt frustrated rather than encouraged when not having implemented or maintained all 14 LiFE activities or when not having reached their desired training results, which could have been reduced by the age-related natural decline of functional capacity. Regarding *outcome expectancies*, participants might have initially been too optimistic about possible intervention effects on their risk of falling. Beneficial intervention effects might have been alleviated by natural deterioration, especially in older participants above 80 years. The fact that levels of *risk perception* towards falling and functional decline were lower at follow-up compared to baseline in both intervention formats aligns with prior research. Blalock et al. (2016) showed that older adults who make efforts to act against their risk of falling show lower levels of perceived fall risk than those who are aware of the recommendations but do not act.

Regarding the variation between levels of *intention*, diary studies have revealed fluctuations of intentions on a daily level for both physical activity and sedentary behavior [40,41]. The fact that participants systematically reported lower levels of intention at the second booster phone call might be due to the end of the intervention. Participants could have been discouraged by managing their training by themselves from that point on.

Both *action and coping planning* showed a similar development over the course of the study, whereas levels of action planning were slightly higher overall. The fact that action planning was promoted in every LiFE and gLiFE session whereas coping planning was only promoted once [24] might have led to participants applying more action than coping planning.

It might also indicate higher increases in underlying psychological determinants with more frequent use of related BCTs in an intervention. Levels of *action control* were significantly higher in LiFE compared to gLiFE throughout the study, except at the time of the second phone call. Action control was mainly operationalized through participants self-monitoring their action plans by ticking boxes in the workbook. Closer trainer supervision in LiFE might have resulted in participants feeling a higher duty to execute action control.

Overall, it seems that LiFE was more successful than gLiFE in increasing levels of volitional determinants such as action planning, coping planning, and action control. The one-on-one implementation of LiFE could have enabled the BCTs to influence the underlying determinants to a greater extent. However, evidence for the effectiveness of BCTs targeting post-intentional processes of behavior change in older age is mixed. Some studies indicate that volitional BCTs might not be adequate for older adults [42]. An important moderator might be whether older adults experience cognitive decline or not, since older adults with strong executive function benefit the most from planning interventions [43]. When considering how older adults with cognitive impairment were not eligible for the study, it seems likely that participants were able to profit from the high amount of planning provided in LiFE and gLiFE.

Habit strength is the most important indicator for behavioral maintenance in LiFE since the LiFE activities should be integrated into daily routines and thereby become habitual. Habit strength was first assessed at the last intervention session, although since this was a novel concept to all LiFE and gLiFE participants, it can be assumed that levels of habit strength were close to zero at the baseline. Both intervention formats showed highest values of habit strength at the last intervention session (T2), with no significant differences between LiFE formats. The fact that participants reported significantly lower values of habit strength at the first booster phone call is contrary to habit theory [14] and empirical evidence [44]. However, after the initial decrease, participants reported stable levels of habit strength above the scale midpoint until the 12-month follow-up, indicating that participants performed the LiFE activities in a manner driven by behavioral automaticity to a significant extent [45]. In

line with this, in a qualitative study which was conducted after 6-month follow up within a subsample of this trial, LiFE and gLiFE participants reported the establishment of new movement habits [46].

LiFE seems to have induced higher values in autonomy, competence, and relatedness from the early stages of the intervention, indicating that LiFE participants felt a higher sense of autonomy, support, and competence through individual trainers. Interestingly, levels of relatedness, which ought to be especially promoted by gLiFE, decreased in gLiFE compared to the LiFE post intervention. gLiFE participants may have felt less related being amongst a group of peers where more potential social contacts were available, whereas LiFE participants had the opportunity to relate to the trainer more closely. In contrast with our findings, a qualitative study on LiFE and gLiFE revealed that gLiFE participants especially valued the interaction with peers [46], whereas other studies found that social interaction was both a facilitator and a barrier for older adults to participate in group-based fall prevention exercises [47]. As a result of fostering autonomy, competence, and relatedness, self-determination theory assumes intrinsic motivation to increase [17]. Since our results revealed that LiFE and gLiFE did not foster the prerequisites of intrinsic motivation, it makes sense that participants did not show increased levels of intrinsic motivation in and of itself.

Limitations

Various limitations of the current study need to be mentioned. First, habit strength was assessed across all LiFE activities. Our results provide no insights into levels of habit strength among the single LiFE activities. Another study on basis of the parent trial revealed differences in the training frequency of the different LiFE activities [48], which could have resulted in the different levels of habit strength. Furthermore, we omitted the assessment of habit strength at baseline because participants had difficulties answering the questions on habit strength in the pre-testing phase and did not (yet) engage in any of the target behaviors (i.e., LiFE exercises). We can only assume that habit strength was (close to) zero prior to the interventions, but a statistical evaluation is impossible here. As another limitation, autonomy, competence, and relatedness were assessed within a closer time frame to the intervention,

providing no conclusions on the long-term effectiveness of LiFE and gLiFE on autonomy, competence, and relatedness. Furthermore, social cohesion was not obtained, although the extent of perceived connectedness between group members could have affected the individual behavior change process. Additionally, the generalizability of our findings is limited because our sample was comprised of only a snapshot of the overall older population, including a higher number of well-educated older adults living in a strong socio-economic area. We also recruited participants who already had fallen or were at risk of falling and screened out those with cognitive impairment. It remains unclear whether LiFE and gLiFE would have induced the same effects on determinants of behavior change in a more diverse sample.

Implications for research and practice

In this study, a first step towards understanding the functioning of LiFE and gLiFE as habit-based interventions for older adults' physical activity promotion and fall prevention was made. These findings might help researchers and practitioners further refine or implement the LiFE and gLiFE intervention in mainly two ways. First, our findings point towards the potential of LiFE and gLiFE in mainly fostering volitional determinants of behavior change, leaving space for refinements regarding motivation and habit strength. Second, practitioners could get a stronger awareness towards fluctuations in psychological determinants and the need for (re-)intervening more flexibly, on the basis of participants' needs.

Future studies are needed to examine the interactions between psychological determinants by considering their temporal resolution [49] and their differential effects on behavioral outcomes. A major challenge in this context is that one BCT can be linked to many different theoretical constructs and vice versa. For example, the BCT "action planning" (1.4.) could be linked to the eponymous construct in the HAPA (Schwarzer, 2008), but it could also be linked to competence in the sense of acquisition of self-regulatory skills as a construct derived from the self-determination theory (Ryan & Deci, 2000). More research, for example using factorial designs, is needed to examine how specific BCTs affect each theoretical construct [50].

Furthermore, it is questionable why both interventions did not result in more remarkable changes in motivational determinants such as self-efficacy or habit strength. The fact that even in the LiFE program as part of which participants receive close supervision did induce decreases in self-efficacy and mid-scale levels of habit strength, raises the question whether an even higher dosage of intervention sessions and or booster sessions would be required for greater effects. However, when planning to modify the 'dosage' of LiFE and gLiFE in future studies cost-effectiveness and potential consequences on large-scale implementability need to be considered as well.

Our findings could help researchers to further refine LiFE and gLiFE, for example by putting a larger focus on autonomy support, which could be especially be important for individuals' long-term maintenance of LiFE. We recommend using the BCT taxonomy in practice for better implementation, transparency and replicability of interventions. Every behavioral intervention consists of BCTs, and knowing which ones are used could help to promote intervention effectiveness.

Regarding practical implications, overall levels of intention were high, indicating that participants were motivated to learn and perform the LiFE activities. This was expected considering that participants were required to respond to the call for participation to enter the recruitment process. Future studies could try to recruit participants via referral from general practitioners or rehabilitation centers to reach older adults who are less motivated.

The frequent assessment of intention, action planning, coping planning, and action control revealed that participants gained new motivation and re-established their volitional strategies by the time of the booster phone calls after an initial decrease. For example, participants could have stopped explicitly planning how to perform the LiFE activities in case of occurring barriers (i.e., coping planning), but where reminded by the booster phone call to do so. Evidence exists on the effectiveness of booster phone calls for improving physical activity [51,52]. Since gLiFE was developed to enable LiFE's large-scale implementability (Kramer, Labudek et al., 2020), the booster phone calls were useful when considering the results of the current study. However, from a practical viewpoint, it may be difficult to keep

the booster phone calls, specifically because of the high number of resources needed to conduct them. To combat this, it is possible that digital solutions such as video group calls could be implemented in the future.

Conclusions

This study was set up to examine the effects of the LiFE and gLiFE interventions on theory-based, psychological determinants of behavior change. In both formats, but especially in the individual LiFE, the BCTs used affected volitional rather than motivational or general determinants of behavior change. Habit strength as an important indicator of the sustainability of the LiFE activities declined post intervention, but then stabilized over time. These study results are an important step towards fully understanding (g)LiFE, as well as other habit-based interventions, fall prevention methods, and physical activity promotion programs.

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Statement of Ethics

Ethics approval for the LiFE-is-LiFE study was obtained from the Ethic Review Board of the Faculty of Behavioral and Cultural Studies at Heidelberg University (study site Heidelberg, document number Schwe2017 2/1–1), and from the Ethic Review Board of the University Hospital and Faculty of Medicine in Tübingen (study site Stuttgart, document number 723/2017BO2) which are both followed the policy and mandates of the Declaration of Helsinki. All participants provided written informed consent.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

Sarah Labudek, Lena Fleig: development of assessments. Carl-Philipp Jansen, Corinna Nerz, Franziska Kramer-Gmeiner, Sarah Labudek: study organization. Michael Schwenk, Clemens Becker: development of the grand proposal for the LiFE-is-LiFE trial. Sarah Labudek: data analysis. Sarah Labudek: draft of manuscript. Lena Fleig, Carl-Philipp Jansen, Franziska Kramer-Gmeiner, Corinna Nerz, Lindy Clemson, Jochen Klenk, Clemens Becker,

Michael Schwenk: critical revision of the manuscript for important intellectual content. All authors have read and approved the final manuscript.

Data Availability Statement

The data used and/or analyzed during the current study are available from the corresponding author on reasonable request. The R script for the analyses can be downloaded under https://osf.io/4rxqt/?view_only=f9ee63d9aba9464fa4d93779fa685abf.

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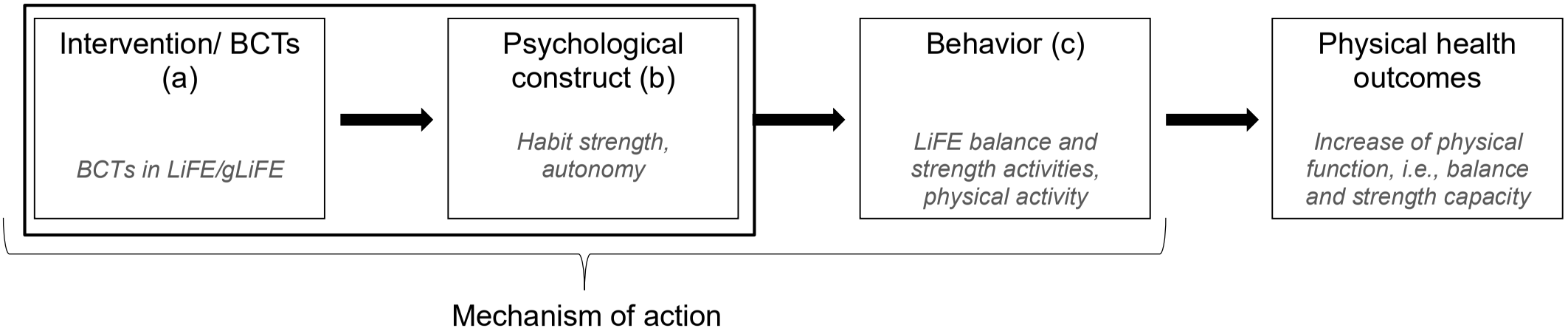
Figure 1

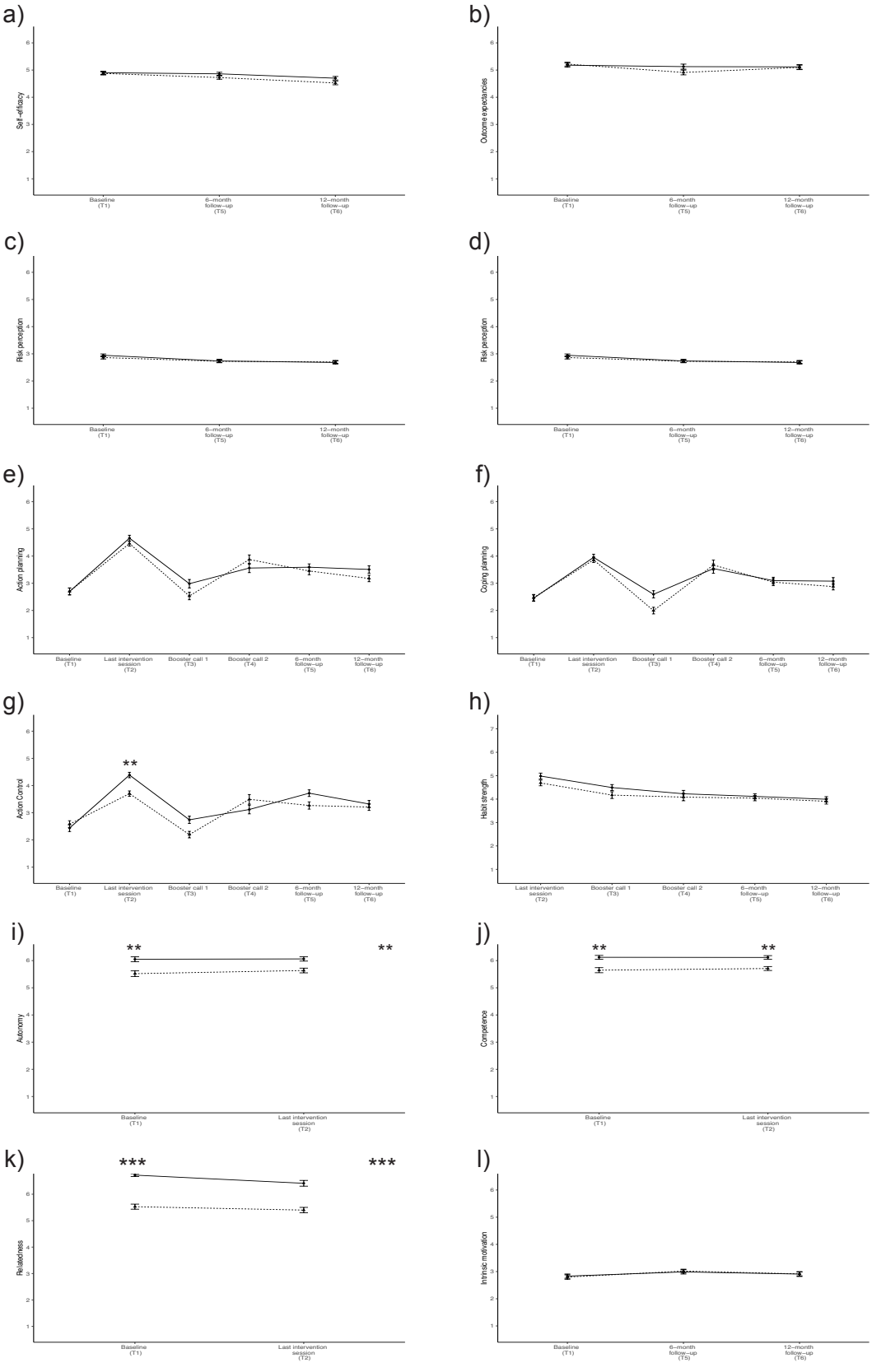
Mechanism of action for health behavior interventions via psychological constructs with examples for the LiFE intervention



Note. Mechanisms of action can include the pathway from the intervention/BTCs via psychological constructs to behavior (a→b→c) or can include the direct path from intervention/BCTs to behavior (a→c). The framed boxes are the focus of this study.

Figure 2

Mean differences and standard errors of psychological determinants of behavior change over time by intervention format



Note: a) self-efficacy, b) outcome expectancies, c) risk perception, d) intention, e) action planning, f) coping planning, g) action control, h) habit strength, i) autonomy, j) competence, k) relatedness, l) intrinsic motivation. The solid line represents LiFE, the dotted line represents gLiFE; asterisk indicates a significant between-group difference at the time point.

Table 1

BCTs used in the LiFE and gLiFE intervention

BCT	Form of delivery (FOD) individual setting (LiFE)	Adapted form of delivery (FOD) group-based setting (gLiFE)	Underlying psychological determinant	Related theory	MBCT	Used in LiFE	Used in gLiFE
1.1. Goal setting (behaviour)	Set the goal to perform a LiFE activity in a specific daily situation		Intention, competence	HAPA, SDT	17	x	x
1.2. Problem solving	Report about implementation of LiFE activities into daily habits at the beginning of each session. Finding solutions for barriers	Exchanging experiences in the group	Coping planning, competence	HAPA, SDT	15	x	x
1.4. Action planning	Write down (self-chosen) implementation intentions into activity planner		Action planning, autonomy, Developing cue-behavior association	HAPA, SDT	6	x	x
1.5. Review behaviour goal(s)	Fine-tuning of action plans in discussion with trainer	Group discussion	Self-efficacy, competence	HAPA, SDT	17	x	x
2.2. Feedback on behaviour	Trainer gives feedback on movement execution of LiFE activities		Self-efficacy, competence	HAPA, SDT		x	x
2.3. Self-monitoring of behavior	Tick the box in activity planner in case of successful performance of action plan		Action control, competence	HAPA, SDT	18	x	x
2.7 Feedback on outcome(s) of behavior	Trainer acknowledges progress in movement execution during repetition of LiFE activities		Self-efficacy, competence	HAPA, SDT	21	x	x
3.1. Social support (unspecified)	Provided by trainers, e.g. praise, support in case of barriers (see 1.2.)	Provided by trainers and peers, scaffolding each other when practicing	Relatedness	SDT	10	x	x
4.1. Instruction on how to perform the behaviour	Demonstration of the LiFE activities (see 6.1.) by trainers and trough LiFE manual		Self-efficacy, competence	SDT	19	x	x
4.2. Information about antecedents	Information about the situational context as a cue for habits		Developing cue-behavior association	Habit-formation theory		x	x

5.1. Information about health consequences	Positive consequences of physical activity and adaptation to training (upgrading)		Outcome expectancies	HAPA		x	x
6.1. Demonstration of the behaviour	Demonstration of the LiFE activities with simultaneous verbal description of correct movement execution by trainers		Self-efficacy, competence	HAPA, SDT	19	x	x
7.1. Prompts/cues	Identification of daily situiations as cues for LiFE activities; session 2: theoretical unit on object-based and situation-based cues		Developing cue-behavior association	Habit-formation theory		x	x
8.1. Behavioural practice/rehearsal	Introduction of two new LiFE activities, their functionality and correct movement execution		Repeating behavior	Habit-formation theory		x	x
8.3. Habit formation	Repeating LiFE activities in stable contexts and thereby developing cue-behavior association		Repeating behavior, developing cue-behavior association	Habit-formation theory		x	x
8.7. Graded tasks	Knowledge on how to upgrade LiFE activities in case of progression or recommendation by trainers		Self-efficacy, competence	SDT	17	x	x
9.1. Credible source	Trainer (as a credible source) explains LiFE activities and principles as well as behavior change concept		Self-efficacy, competence	SDT		x	x
10.4. Social reward	Positive reinforcement in case of success by trainers	By trainers and peers	Relatedness	SDT	8	x	x
12.1. Restructuring the physical environment	Positioning cues for performing the LiFE activities at salient places or placing notes to remember the LiFE activities		Developing cue-behavior association	Habit-formation theory		x	x
15.1. Verbal persuasion about capability	Tell participants that they can succeed with integrating the LiFE activities into daily routines even when it seems challenging in the beginning		Self-efficacy, competence	HAPA, SDT		x	x
15.2. Mental rehearsal of successful performance		Visualizing movement execution in specific daily situation at home	Self-efficacy, competence	HAPA, SDT			x
15.3. Focus on past success	Praise by trainers in case of successes during the week		Self-efficacy (a)			x	x

Table 2

Scales, points of measurement, and exemplary items of psychological determinants of behavior change

Construct	No. of items	Scale	Points of measurement	Cronbach's alpha*	Example
Self-efficacy	6	1-6	3	.78 - .84	I am sure that I can integrate more physical activity into my daily routines.
Outcome expectancies	2	1-6	3	.62 - .68	If I practice LiFE regularly, then I prevent falls.
Risk perception	4	1-5	3	.80 - .82	Compared to other persons of my age and sex, my chances of falling is …
Intention	2	1-6	6	.47 - .86	I intend to live an active lifestyle.
Action Planning	3	1-6	6	.86 - .94	In the past four weeks, I have made a detailed plan how I can integrate more physical activity into my daily life.
Coping Planning	3	1-6	6	.88 - .93	In the past four weeks, I have made a detailed plan how I can be physically active even if something else comes up.
Action Control	3	1-6	6	.52 - .90	In the past four week, I thoroughly took care of doing my LiFE activities as I planned them.
Habit strength	4	1-7	5	.88 - .90	The LiFE activities are something I do automatically.
Autonomy	3	1-7	2	.67 - .73	I feel I have the opportunity to make choices with respect to the way I do the LiFE program.
Competence	4	1-7	2	.75 - .86	I feel I very effectively execute the exercises of the LiFE program.
Relatedness	1	1-7	2	-	I feel connected to the people I interact with in the LiFE program.
Intrinsic motivation	4	0-4	3	.84 - .87	I am physically active because it is fun

Note: *in case of two items, the bi-variate correlation is reported instead of Cronbach's alpha

Table 3

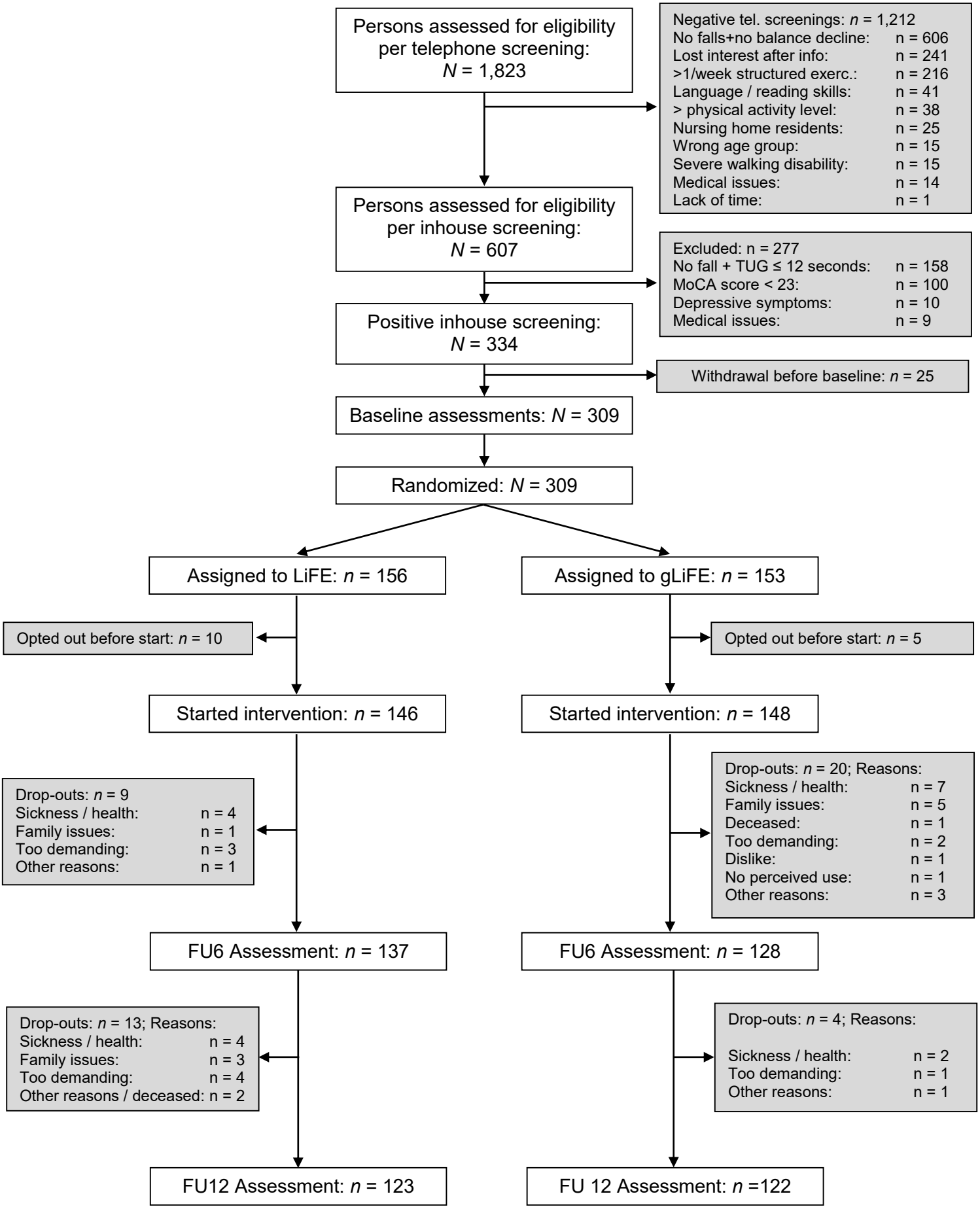
Sample characteristics for LiFE and gLiFE participants included in the analyses

	All	LiFE	gLiFE
N (mean ± SD)	*N* = 294	*N* = 148	*N* = 146
Age, years	78.9 ± 5.3	78.9 ± 5.2	78.8 ± 5.5
Sex, n (%) female	216 (73.5)	110 (74.3)	106 (72.6)
BMI [kg/m²]	27.2 ± 4.9	27.7 ± 5.0	26.7 ± 4.7
Cognitive status (MoCA Score)	26.0 ± 2.0	26.1 ± 2.0	25.9 ± 2.0
% of fallers in past six months	120 (40.8)	60 (40.5)	60 (41.1)
Concerns about falling (Short FES-I)	10.4 ± 3.0	10.4 ± 3.1	10.3 ± 2.9
Years of education	13.8 ± 3.9	13.6 ± 3.9	14.0 ± 3.9

Note. MoCA: Montreal Cognitive Assessment, assesses cognitive status, higher scores indicating better cognitive stats (max. 30 points); FES-I: Falls Efficacy Scale International, displays concerns about falling with scores from 7 (‘not concerned about falling’) to 28 points (‘very concerned about falling’)

Supplement 1

Participant flow for the LiFE-is-LiFE trial



Supplement 2

Means, standard deviations, and correlations for LiFE at baseline and follow-up

Pre intervention	*M*	*SD*	1	2	3	4	5	6	7	8	9	10	11
1. Self-efficacy	4.90	.68											
2. Outcome expectancies	5.18	.90	.50**										
3. Risk perception	2.95	.59	-.07	.01									
4. Intention	5.09	.80	.46**	.44**	.05								
5. Action planning	2.70	1.52	.06	.02	.09	.04							
6. Coping planning	2.45	1.44	-.10	-.05	.03	-.09	.73**						
7. Action control	2.44	1.56	.08	-.04	.04	.09	.62**	.60**					
8. Habit strengtha	4.98	1.51	.18*	.29**	-.09	.10	.12	.15	.24**				
9. Autonomyb	6.05	1.06	.26**	.37**	-.14	.28**	.06	-.03	.06	.29**			
10. Competenceb	6.12	.84	.28**	.29**	-.15	.18*	.09	-.07	.06	.30**	.66**		
11. Relatednessb	6.72	.64	.22**	.21**	-.13	.13	.08	-.07	.04	.26**	.52**	.52**	
12. Intrinsic motivation	2.83	.95	.23**	.22**	-.23**	.33**	.16	.11	.28**	.15	.27**	.17*	.19*

Follow-up	*M*	*SD*	1	2	3	4	5	6	7	8	9	10	11
1. Self-efficacy	4.70	.71											
2. Outcome expectancies	5.13	1.02	.35**										
3. Risk perception	2.68	.61	-.29**	-.34**									
4. Intention	4.94	.86	.58**	.34**	-.19*								
5. Action planning	3.51	1.51	.37**	.17	.02	.39**							
6. Coping planning	3.08	1.44	.20*	.12	-.06	.19*	.61**						
7. Action control	3.32	1.43	.33**	.20*	-.11	.34**	.57**	.64**					
8. Habit strength	3.99	1.24	.45**	.35**	-.24**	.35**	.37**	.24**	.42**				
9. Autonomyc	6.06	.95	.37**	.47**	-.19*	.21*	.18*	.17	.18*	.32**			
10. Competencec	6.12	.80	.36**	.49**	-.21*	.34**	.07	.04	.20*	.33**	.71**		
11. Relatednessc	6.41	1.28	.07	.20*	-.13	.02	-.06	-.01	.12	.13	.27**	.29**	
12. Intrinsic motivation	2.91	1.00	.30**	.18*	-.24**	.37**	.26**	.18*	.28**	.26**	.23*	.16	.04

Means, standard deviations, and correlations for giFE at baseline and follow-up

Pre intervention	*M*	*SD*	1	2	3	4	5	6	7	8	9	10	11
1. Self-efficacy	4.88	.68											
2. Outcome expectancies	5.22	.87	.28**										
3. Risk perception	2.86	.64	-.02	-.19*									
4. Intention	5.12	.86	.49**	.29**	-.04								
5. Action planning	2.70	1.55	.17*	.19*	-.07	.23**							
6. Coping planning	2.47	1.42	.11	.11	.00	.09	.73**						
7. Action control	2.58	1.52	.18*	.09	-.06	.20*	.69**	.58**					
8. Habit strengtha	4.69	1.39	.11	.14	-.04	.05	.21*	.28**	.20*				
9. Autonomyb	5.52	1.13	.19*	.42**	-.03	-.02	.16	.13	.08	.41**			
10. Competenceb	5.65	1.03	.25**	.21*	-.11	.12	.22*	.17	.14	.44**	.65**		
11. Relatednessb	5.53	1.52	.19*	.12	-.04	-.06	.14	.06	.12	.41**	.50**	.49**	
12. Intrinsic motivation	2.80	.98	.15	.26**	-.26**	.26**	.29**	.15	.21*	0.09	0.11	0.11	0.09

Follow-up	*M*	*SD*	1	2	3	4	5	6	7	8	9	10	11
1. Self-efficacy	4.53	.75											
2. Outcome expectancies	4.91	.98	.45**										
3. Risk perception	2.70	.63	-.14	-.21*									
4. Intention	4.83	.92	.63**	.50**	-.22*								
5. Action planning	3.18	1.33	.27**	.15	-.14	.24**							
6. Coping planning	2.88	1.38	.28**	.26**	-0.10	.18*	.72**						
7. Action control	3.21	1.37	.43**	.26**	-.27**	.35**	.57**	.54**					
8. Habit strength	3.91	1.32	.39**	.33**	-.13	.31**	.28**	.35**	.25**				
9. Autonomyc	5.64	1.00	.43**	.38**	-.12	.40**	.22*	.24*	.23*	.31**			
10. Competencec	5.71	.84	.40**	.40**	-.11	.28**	.13	.25**	.21*	.37**	.63**		
11. Relatednessc	5.32	1.52	.14	.15	.05	.15	.05	.18	.09	.14	.32**	.37**	
12. Intrinsic motivation	2.91	.80	.26**	.24**	-.34**	.28**	.31**	.33**	.35**	.23**	.36**	.39**	.13

Note. M and *SD* are used to represent mean and standard deviation, respectively. All values are taken from the first and last measurement point available, which is baseline and 12-month follow-up assessment, despite stated otherwise. [a] assessed at the last intervention session; [b] assessed at the second intervention session; [c] assessed at the last intervention session * indicates $p < .05$. ** indicates $p < .01$.