

A multicenter controlled study for dementia prevention through physical, cognitive and social activities – GESTALT-kompakt

Anna Streber
Karim Abu-Omar
Christian Hentschke
Alfred Rütten

Department of Sport Science and Sport, Faculty of Humanities, Social Sciences, and Theology, Friedrich-Alexander-University of Erlangen-Nürnberg, Erlangen, Germany

Abstract: Prevention of dementia is a public health priority. Physical activity (PA) can reduce the risk of dementia, but the majority of people remain sedentary. We conducted a multicenter controlled study with older adults (60+ years). We hypothesized that an evidence-based PA intervention – GEhen, Spielen und Tanzen Als Lebenslange Tätigkeiten – kompakt [walking, playing and dancing as lifelong activities-compact] (GESTALT-kompakt) – would lead to significantly larger improvements in PA levels (step counts/Fitbit Zip™), cognitive functions (DemTect) and social activities (Social Activity Log), compared to an active control group. Data were collected at baseline and after 3 and 12 months. The intervention group received a 12-week (1/week) multimodal and multicomponent PA program, which combined PA with cognitive and social activities. The control group received either regular gymnastics or cognitive training (1/week). A mixed linear model was chosen for analysis. A total of 87 older individuals were recruited in the GESTALT-kompakt study (68 females, average age = 76.0 years, SD ± 9.2, range 52–95 years). Marginally significant differences were observed in the intervention group (n=57) in comparison to the control group (n=30), regarding improvements in PA (difference of mean changes = 866.4 steps, $p=0.055$) after 3 months. However, their PA decreased to the baseline score value after 12 months (–866.0 steps, $p=0.061$). GESTALT-kompakt did not cause significant differences in cognitive functioning (–0.8620, $p=0.074$) and social activities (–0.2428, $p=0.288$) in comparison to the control intervention from T0 to T1. Sixteen (24.2%) study participants who finished T2 reported a negative life event during the follow-up period, which severely influenced their PA behavior. GESTALT-kompakt might be effective in increasing PA in the short term, but did not have a long-term impact on the PA levels, cognitive functions or social activities of the participants. We recommend PA programs with longer duration to change behavior in the long term.

Keywords: aging, intervention, physical activity program, cognitive function, social activity, dementia

Background

Dementia has become a global health problem, and it is increasingly recognized as being a high public health priority.¹ G8 member state meetings in 2013 and the Dementia Summit in 2014² concluded that the prevention of dementia should become the main focus in public health policies and actions to counteract the dementia epidemic. Recent studies have shown the importance of tackling the impairment of cognitive abilities in dementia with neuropsychologic interventions.^{3–5} But Wu et al give the policy implication that it is primary prevention that has the largest effect on reduction of occurrence of later dementia and disability.⁶

Correspondence: Anna Streber
Department of Sport Science and Sport,
Friedrich-Alexander-University of
Erlangen-Nürnberg, Gebbertstraße 123b,
D-91058 Erlangen, Germany
Tel +49 9131 852 5000
Fax +49 9131 852 5002
Email anna.streber@fau.de

The promotion of a healthy lifestyle, including being a nonsmoker, having a body mass index between 18 and 25, high fruit and vegetable intake, regular physical activity (PA) and low/moderate alcohol intake, is one of the key strategies to reduce the incidence of dementia. The Caerphilly Cohort study, which followed over 2,000 males over 30 years, showed that a healthy lifestyle, based on four out of five healthy behaviors, can reduce the incidence of dementia by 60%.⁷ Especially, the promotion of PA and, in particular, regular physical exercise training may have the potential to reduce the risk of dementia onset. On the one hand, research results indicate that ongoing, lifelong, moderate-intensity physical exercise behavior and varying leisure time activities have the potential to prevent the risk of dementia.^{8,9} On the other hand, a systematic review and expert consensus identified physical inactivity as an important risk factor and potentially modifiable prevention target next to other modifiable risk factors such as depression, (midlife) hypertension, diabetes, (midlife) obesity, hyperlipidemia and smoking behavior.¹⁰ Nonmodifiable risk factors for dementia are age, genetic disposition and gender.¹¹

The mechanisms by which PA affects the onset of dementia are complex and multifactorial. PA tackles comorbidities such as cardiovascular diseases, depression and type II diabetes,^{12–16} which are known to contribute to vascular and neurodegenerative dementia.¹⁷ Regarding cognitive functions, PA interventions have been developed and tested in controlled trials that demonstrate positive effects on cognitive functioning in older people,^{8,18–20} even though there is conflicting evidence.²¹ Recent evidence has shown that the combination of cognitive and physical training might be more effective for preventing dementia than the training of just one of both.^{22,23} The combination of PA with cognitive challenges might be particularly effective in inducing beneficial prevailing effects on the brain structure and function, due to the facilitating effects on learning through PA (eg, angiogenesis, availability of certain neurotrophins) and the neuronal changes induced through cognitive training.²⁴ To enhance cognitive performance and overall function in older adults, evidence supports structured, multicomponent exercise programs with long durations.²⁵ Besides a physically active lifestyle, a socially integrated lifestyle in late life may also have the potential to prevent dementia.²⁶ In the field of social relationships, low social participation, more loneliness and less frequent social contact were statistically significantly associated with incident dementia.²⁷ Thus, the best strategy to reduce the risk of cognitive impairment might be interventions that include cognitive, social and physical components.^{24,28}

Despite increasing evidence for the protective effects of PA on the development of dementia, the majority of people remain sedentary. Data from the Eurobarometer indicate that across Europe, only 10% of respondents aged 55–69 and only 8% of respondents aged 70 years and older engage in regular PA.²⁹

A major challenge is the development and implementation of effective dementia prevention programs for the health care system. In Germany, standard prevention protocol lacks specific PA programs for dementia prevention, based on the latest evidence (eg, multimodal including physical, social and cognitive activities). Standard prevention programs comprise short-term courses that last a maximum of 12 weeks (1x/week) and only address single mechanisms as outlined earlier.

In this regard, we developed the GESTALT (GEhen, Spielen und Tanzen Als Lebenslange Tätigkeiten [walking, playing and dancing as lifelong activities]) intervention, which is an evidence-based, multimodal PA program that combines PA with cognitive and social activities and comprises behavior change techniques to empower participants to initiate and maintain regular physical, cognitive and social activities in the long term.

GESTALT

The multimodal PA intervention GESTALT^{30,31} comprises the latest evidence for dementia prevention through systematically integrating cognitive training (eg, memory training, step sequences) and social/emotional interaction (eg, conviviality, body contact) into a PA program (eg, endurance, strength, postural balance). This group-based program has been designed to target the sedentary lifestyle of older adults and to engage them in the World Health Organization's recommended 150 min of moderate-intensity PA per week³² as well as in types of exercises that are known to be especially effective, such as dancing.³³

To fit the existing conditions for federal subsidies for prevention programs in Germany, the original GESTALT program was adapted.^{30,31} Preserving the core elements and foundations of GESTALT, we developed a 12-week version of the original program – GESTALT-kompakt [compact]–to be suitable for financial support from German health insurances (80% of the participant fee is refundable [twice a year] by German health insurances if the participant was joining the primary prevention program on a regular basis; for this, the program has to meet several requirements) and, therefore, to be sustainably implemented in real-world prevention practice.

The major aim of this study was to analyze the short- and long-term effectiveness of the GESTALT-kompakt program compared to the standard prevention approach in Germany in real-world settings. We hypothesized that in older adults, the program GESTALT-kompakt would result in a significantly higher increase in PA (primary outcome) until the end of the intervention (3 months) and until the follow-up after 12 months, in comparison to the control group. We further hypothesized that GESTALT-kompakt would lead to significantly larger improvements in cognitive functions and social activities (secondary outcomes), compared to the control group.

Subjects and methods

Study design and procedures

The GESTALT-kompakt study is an effectiveness study in between the endpoints of being pragmatic and explanatory.³⁴ Accordingly, the Pragmatic–Explanatory Continuum Indicator Summary and Pragmatic–Explanatory Continuum Indicator Summary 2 were used for study design (Table 1).^{35,36}

The emphasis on measuring effects in real-world settings was chosen because of its importance for sustaining the intervention in practice to create a public health impact. In this regard, implementation and evaluation were framed in a participatory process involving all relevant stakeholders.³⁷

The GESTALT-kompakt study is a multicenter controlled study for dementia prevention, tackling multiple risk factors through a multicomponent intervention. Overall, five intervention and three control groups were involved in two settings (community-based and assisted living). Due to practicability reasons in the settings, no randomization or blinding of either participants or evaluators was conducted. Participants gave written informed consent at baseline.

Target group and recruitment

The target group consisted of individuals (60+ years) at risk for dementia with one or more modifiable risk factors (see the “Background” section) which were assessed at baseline. As usual in prevention practice, there were no explicit inclusion

Table 1 Classification of GESTALT-kompakt on the PRECIS 2³⁶ continuum

PRECIS 2 domains	Score	Rationale
Eligibility criteria	5	All people who responded to recruitment were allowed to participate in the study (no exclusion criteria). The reference value for age was 60 years and older, but persons were not excluded if they were younger
Recruitment path	4	Usual paths of prevention providers were used to recruit participants. But providers were supported by the project coordinator providing materials and contents
Setting	5	Identical settings to usual prevention care were chosen as the intervention was taking place in the venues of five prevention providers (two in the setting of assisted living and three in a community setting). Equal for control groups
Organization intervention	4	Identical organizations to usual practice were chosen. Organizations did not require more than usual experience and no increase of resources. Physical activity trainers (provided by the organizations themselves) had to join an additional training before implementing GESTALT-kompakt
Flexibility of experimental intervention – delivery	2	Trainers had to follow a strict protocol (trainer manual) regarding the content of the intervention and fill in a short feedback protocol for each session for the head of project. Only small adaptations of contents regarding the health status and physical activity levels of participants in the different settings were allowed
Flexibility of experimental intervention – adherence	4	There was no more than usual encouragement to adhere to the intervention. Participants who missed class more than once were called and asked for the reason. Trainers were keeping an attendance list to document how many sessions (max 12) the participants were joining. Participants were not excluded if they were not adherent
Follow-up	1	Participants were passing three measurements (pre/post/follow-up) of their physical, cognitive and social activities during the study. Participants were having two additional, scheduled follow-up visits by the researchers, particularly for intervention-related data collection. In usual practice, no follow-up visits are carried out
Outcome	5	Primary outcome – increase of physical activity – was commonly chosen by prevention providers and scientists and is easy for the participants to comprehend
Analysis	5	All available data were used for analysis
Mean value	3.89	

Note: Likert scale 1–5 (1= very explanatory, 2= rather explanatory, 3= equally, 4= rather pragmatic, 5= very pragmatic).

Abbreviations: GESTALT, GEhen, Spielen und Tanzen Als Lebenslange Tätigkeiten [walking, playing and dancing as lifelong activities]; PRECIS, pragmatic–explanatory continuum indicator summary.

or exclusion criteria. The target group was recruited from the general population and the assisted living facilities.

Prevention providers recruited participants for the intervention group from November 2014 until February 2015. Applied strategies were: flyer (5/5 providers), placards (5/5), information event (4/5), local newspaper article (3/5), promotion video (3/5), advertisement in program booklet of provider (2/5) and letter to residents in assisted living (1/5). Providers were supported by the project coordinator who provided the listed material and contents. To ensure the recruitment of target group participants, the material emphasized a present lower level of PA. The control group interventions were regular offers provided in real-world prevention practice. Participants for the control groups were, therefore, independently recruited through established strategies of providers, such as entry in the program booklet and word-of-mouth advertising.

Intervention and providers

GESTALT-kompakt as well as the control interventions were carried out by five prevention providers in Bavaria, Germany. Three of them worked in the community-based setting (sports club, protestant education institute, local sports department – providers 1–3) and two providers were from assisted living facilities (providers 4 and 5). Providers were selected by the project coordinator to ensure a mix of settings and organizations. Instructors were eligible if they were employed by the provider, qualified exercise instructors and interested in the program. A description of qualification, age, gender and professional experience of instructors for the intervention and control groups is provided in Table 2.

Intervention group

The GESTALT-kompakt intervention is a multimodal PA program with 12 sessions. Each session lasts 90 min once a week and includes two accompanying modules. Module 1 is an evidence-based multimodal PA program integrating social and cognitive activities (60 min). Module 2 is a PA coaching program (30 min).

Module 1 contains PA in daily routines and walking (eg, walking through activity trails), sports and games (eg, playing with balloons and balls) and dance and movement to music (eg, line and square dance). Different materials, contents and didactic methods are used to create various demands, mainly for the endurance and coordination of participants. Module 2 aims to enable participants to transfer and maintain the recommended PA level into their daily lives. The main contents are mood and barrier management, rewarding strategies, goal setting and knowledge transfer and address PA preferences of participants. Table 3 shows the outline of GESTALT-kompakt with its structure and main contents.

The program is divided into four stages. During the first 3 weeks (stage 1), participants get to know the program, the teacher and each other, and gather first experiences in movement. From here on, the weekly instructed sessions are complemented with additional tasks and experiences for participants to foster the aims of the intervention: During stage 2 (weeks 4–6), participants receive tasks to practice at home. During stage 3 (weeks 7–9), the whole group additionally takes part in three excursions with their instructor in the near surrounding, in order for the participants to get to know further PA offers. Stage 4 (weeks 10–12) participants additionally have three excursions in smaller groups without their instructor.

Table 2 Description of the instructors of GESTALT-kompakt and control groups

	Provider 1	Provider 2	Provider 3		Provider 4	Provider 5
Group	CG and IG	CG and IG	IG	IG	CG	IG
Gender	F	F	F	F	F	M
Age (years)	49	58	46	47	66	46
Years of professional experience as physical education teacher	25	35	7	13	8	4
Years of experience working with elderly	25	35	6	12	8	17
Qualification	State-certified physical education teacher	Licensed by BLSV	Dipl. Pedagogue (sports and psychology)	Licensed by BLSV	Licensed by BVGT	Licensed by BLSV
Previous experience with GESTALT	None	None	None	Trainer of a previous group	None	None
Employment relationship in GESTALT-kompakt	Freelancer	Freelancer	Freelancer	Freelancer	Freelancer	Freelancer
General employment	Freelancer	Freelancer	Office worker (part time)	Office worker (part time)	Retired	Geriatric nurse

Abbreviations: BLSV, Bayerischer Landes-Sportverband eV; BVGT, Bundesverband Gedächtnistraining eV; CG, control group; GESTALT, GEhen, Spielen und Tanzen Als Lebenslange Tätigkeiten [walking, playing and dancing as lifelong activities]; IG, intervention group; f, female; m, male.

Table 3 Outline of the GESTALT-kompakt intervention

Session	Stage	Module 1		Module 2 coaching and theory
		Topic of PA session	Main PA content	
1	Stage 1: To get to know each other and gain first experiences of movement	Get to know each other through movement and play	Games with balloon	Goals of intervention and dementia prevention
2		Gather experience with different materials to music	Square dance	Advantages of PA for prevention and Borg-scale
3		Gather experience with materials in an activity trail	Activity trail	Motives for participation in course and PA
4	Stage 2: Preparation of the transfer into everyday life	Play together – Part I + impulse for activities at home	Games with balloon	Goal setting I
5		Move together – Part I + impulse for activities at home	Endurance and coordination	Goal setting II and function of the memory
6		Walk together – Part I + impulse for activities at home	Walking with memory tasks	Mood and barrier management
7	Stage 3: Transfer into everyday life	Play together – Part II + excursion with instructor	Games with parachute	Barrier plan I
8		Move together – Part II + excursion with instructor	Line dance	Barrier plan II and rewarding strategies
9		Walk together – Part II + excursion with instructor	Walking symbols	Added value of being active
10	Stage 4: Sustainability and self-determination	Play together – Part III + independent excursion	Games with balls, wooden staff and towels	Information about offers and suitable types of activity
11		Move together – Part III + independent excursion	Endurance and coordination	Social support
12		Walk together – Part III + independent excursion	Walking with different materials	Reflection of the course and changes in PA behavior

Notes: Main focus: red = playing; green = dancing; blue = walking.

Abbreviations: GESTALT, GEhen, Spielen und Tanzen Als Lebenslange Tätigkeiten [walking, playing and dancing as lifelong activities]; PA, physical activity.

To implement GESTALT-kompakt, qualified PA instructors were trained in a 2-day seminar by the principal investigator. They were given a written instructors manual containing an extensive description of each PA session (goals, didactics, content, timeline, materials and essentials) including instructions for the PA coaching.

Control group

Three independent groups – one memory training and two PA groups – served as control groups. All sessions were group based, took place once a week and lasted 45–60 min. Main contents of memory training were brainteasers and riddles while sitting. One PA group did movements during sitting and standing, while the other did moderate-intensity gymnastics and strength training with small equipment. In all sessions, there was no simultaneous performance of physical and cognitive tasks. The intervention group instructors also carried out the control group sessions.

Ethical approval

Ethical approval for research within GESTALT was granted by the Bavarian Health and Food Safety Authority, the project agency of the Bavarian State Ministry of the environment and public health.

Outcome measures

All assessments were undertaken at the beginning (T0), at the end (T1) and 12 months after the beginning of the intervention (T2), respectively.

Physical activity

To measure the PA levels, the participants wore a waist-mounted pedometer (Fitbit Zip™ [advantages {especially for older adults}: no charging, no turning off and on, no reading and note down of steps required, relatively low costs, 7-day memory, high practicability]) during waking hours for 7 consecutive days at all three points of measurement. The Fitbit Zip has proven to be a valid activity monitor to measure PA.³⁸ Participants were asked to continue with their typical activities and to remove the pedometer only while bathing, showering or swimming. Simultaneously, participants kept a PA diary and noted any incidence of, for example, illness. At T2, a written form was added to the diary, which asked the participants to report any negative life events (eg, falls, fractures and surgeries) since T1 that influenced their PA behavior. The diary was pretested in a small group of older adults (n=10) to learn about its usability and meaningfulness for this target group. Minor changes were made regarding the font size, and valuable

information was gathered regarding handling and difficulties filling in the diary.

For analysis, the pedometer data (day-end steps taken) were summed and divided by the number of days it was worn to compute the mean steps per day. To be representative, all days were screened if the pedometer had been worn at least 8 h per day without major gaps (>6 h). Missing days (unrecorded data) or unrepresentative days (illness and holidays) were excluded. Participants had to have at least 3 valid days out of 7 days of measurement. No distinction was made between workdays and weekends. To interpret the PA levels, the mean steps were assigned to the categories of the graduated step index (steps/day: <2,500= basal activity; 2,500–4,999= limited activity; 5,000–7,499= low activity; 7,500–9,999= somewhat active; 10,000–12,499= active; \geq 12,500= highly active) of Tudor-Locke et al.³⁹ Participants rated their satisfaction with the program on a five-point Likert scale at the end of the intervention.

Cognitive functions

The DemTect was used to measure cognitive functioning. It is valuable for detecting and differentiating cognitive dysfunction when symptoms begin.⁴⁰ It contains five subtests: word list (short-term verbal memory), transcoding of numbers (executive function), supermarket task (word fluency), digit span reverse (short-term and working memory) and delayed recall of wordlist (long-term verbal memory). Results are transformed via a scoring routine and summed up to a total score (0–18 points). For interpretation, high values indicate good cognitive functioning. With a cutoff of 13 points (for mild cognitive impairment), the DemTect has a high sensitivity (97.6%) and specificity (92.9%) to detect possible cognitive impairment.⁴¹ A good retest reliability was shown.⁴² To reduce recall bias, two available versions of the test were used alternately.

Social activity

The concept of social health is multifaceted and hard to measure.⁴³ As GESTALT-kompakt participants were partly free living and partly in assisted living, the instrument had to mirror both living conditions.

The “Social Activity Log” questionnaire was designed to capture the frequency and diversity of social activities outside of daily responsibilities.⁴⁴ As there was no German version available, the questionnaire was translated into German (process: translation by a native German speaker; retranslation by a native English speaker; final corrections by scientific board). The scoring manual was provided by the original authors. The Social Activity Log comprises 13 items and

three subscales, which categorize activities into “low contact”, “moderate contact”, and “contact per mail or phone”. It provides subscale mean scores and a total mean score (0–6 points). Higher values indicate more social activity.

Statistical analysis

For statistical analysis of the primary and secondary outcomes, a mixed linear model was chosen, which is particularly suitable for the analysis of longitudinal data resulting from the time-repeated observation of individuals in the context of longitudinal studies. The mixed linear model used is based on a 3×2 factorial design with three time points and two groups (intervention vs control). Time effects from baseline to the first and from the first to the second measurement time point, group effects and interactions between time and group were considered as fixed effects and intercept and slope were considered as random effects in the model. Here, the linear change from T0 to T1 is relevant for the effect within the intervention phase. The linear change from T1 to T2 is relevant for the effect in the follow-up phase. In addition, differences in the overall effect of the intervention over both phases were tested. For this purpose, the given statistical model (hypothesis model), containing the main effects and the interaction effects of the two phases of the factor “time” by the factor “group”, was compared to a model (zero model) that only contained the main effects of the above-mentioned factors in a likelihood ratio test. The primary analysis was not adjusted for other covariates.

Missing values were not replaced. However, the mixed linear model does enclose all available information into the analysis. Results are, therefore, undistorted under a missing at random assumption.

Results

Sample characteristics

Eighty-seven people joined the study. Fifty-seven pertained to the intervention group and 30 to the control group. Dropout reasons are shown in the participant flow diagram (Figure 1). Three participants were excluded from the analysis because of prevalent dementia at baseline.

Baseline characteristics (Table 4) differed regarding the PA levels (mean steps/day were lower in the control group as in the intervention group). Control group participants were more prone to using a walking aid, having heart complaints, suffering from mild cognitive impairment, having a pulmonary disease and suffering from allergies. GESTALT-kompakt participants were more prone to suffering from depression and living alone. Further, our group of participants represents the Bavarian population for this age group.^{45,46}

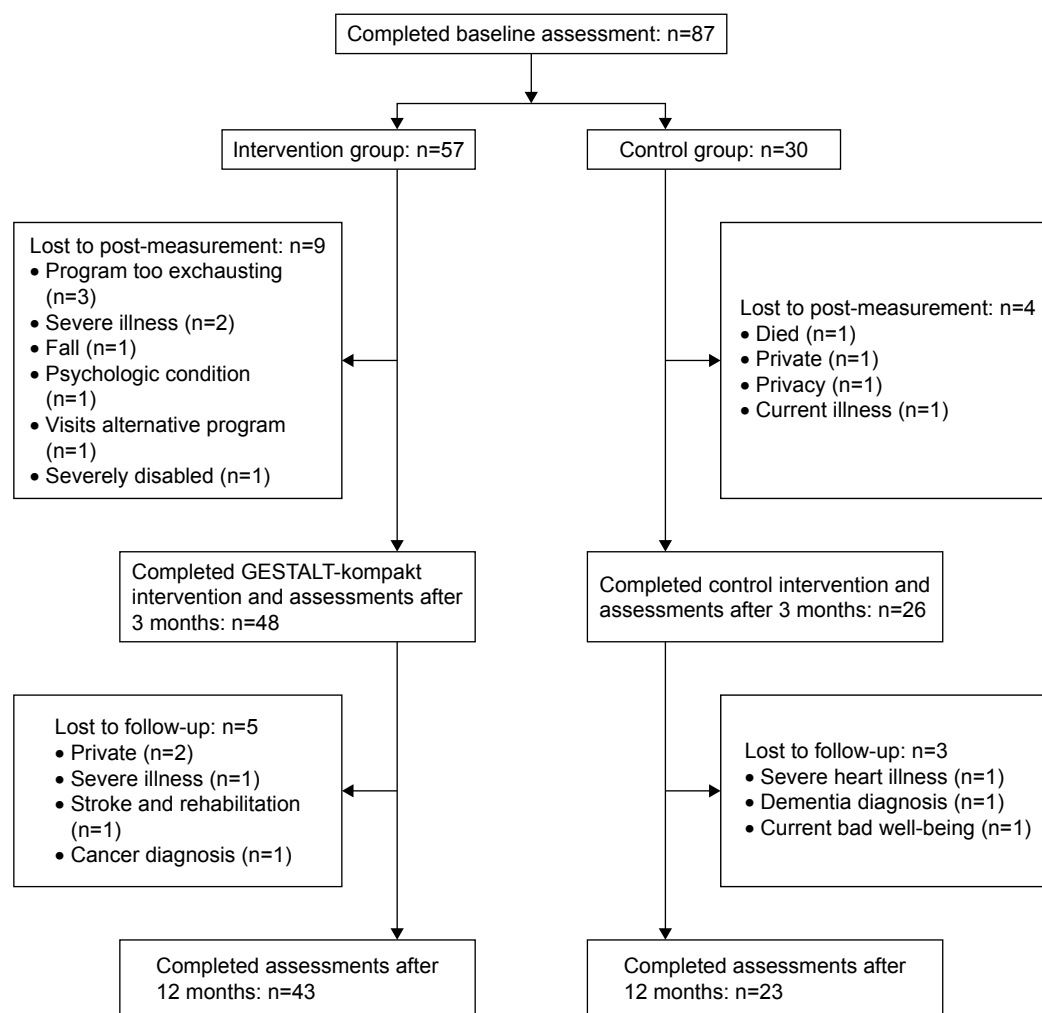


Figure 1 Flow diagram of the study.

Abbreviation: GESTALT, GEhen, Spielen und Tanzen Als Lebenslange Tätigkeiten [walking, playing and dancing as lifelong activities].

Compliance, program satisfaction and study protocol deviations

On average, participants of the intervention group who completed the program joined 10.2 (SD ± 1.6) out of 12 PA sessions (85.0%) and 2/3 (66.6%) excursions with their instructor. Control group participants joined 9.8 (SD ± 2.3) out of 12 sessions (81.7%).

On a five-point Likert scale, 32 (66.7%) of the GESTALT-kompakt participants stated that they were very satisfied, 15 participants (31.3%) were satisfied, 1 person (2.1%) was neutral and no one stated to be dissatisfied or very dissatisfied with the program.

Regarding the study protocol, the content of the PA program was meanwhile adapted to the higher age and severe physical limitations (eg, walking limitations) of the participants in the two assisted living facilities. Some tasks were performed while sitting instead of standing. The other three intervention groups adhered to the program.

Outcomes

Mean values and standard deviations for all points of measurement and outcomes are shown in Table 5. All time and interaction effects for the measured outcomes are shown in Table 6.

Physical activity

At 3 months, there was a significant increase in the average number of steps in the intervention group, but not in the control group. However, the interaction effect was not significant (866.4 steps, $p=0.055$). From T1 to T2, there was no significant interaction effect, but a significant decrease in steps was detected in the intervention group. There was no overall effect of the intervention on the PA of participants over both phases.

Looking at the assignment to the graduated step index³⁹ (Figure 2), one can see from which category to which category the changes in mean steps have occurred. In the intervention

Table 4 Baseline characteristics of GESTALT-kompakt and control group participants

Baseline characteristics n (%)	Total sample n=87	IG n=57	CG n=30
Nonmodifiable risk factors			
Age (years), mean (SD)	75.98 (9.2)	73.47 (10.1)	78.30 (6.7)
Gender (female)	68 (78.2)	45 (79.0)	23 (76.7)
Physical activity behavior			
Sedentary ^a	36 (41.4)	21 (36.8)	15 (50.0)
Walking aid ^b	17 (19.5)	9 (15.8)	8 (26.7)
Cardiovascular factors			
Overweight ^b	41 (47.1)	28 (49.1)	13 (43.3)
High blood pressure ^b	48 (55.2)	31 (54.4)	17 (56.7)
Heart complaints ^b	25 (28.7)	13 (22.8)	12 (40.0)
Feeling pressure in chest while being active ^b	13 (14.9)	10 (17.5)	3 (10.0)
Diabetes ^b	14 (16.1)	8 (14.4)	6 (20.0)
History of stroke ^b	1 (1.2)	1 (1.75)	0 (0)
Arterial disturbed blood circulation ^b	5 (5.8)	2 (3.5)	3 (10.0)
Venous disturbed blood circulation ^b	28 (32.2)	20 (35.1)	8 (26.7)
Self-reported medical disorders			
Depression ^b	7 (8.1)	6 (10.5)	1 (3.3)
Mild cognitive impairment ^c	17 (19.5)	9 (15.8)	8 (26.7)
Dementia ^d	3 (3.5)	2 (3.5)	1 (3.3)
Carcinoma ^b	5 (5.8)	3 (5.3)	2 (6.7)
Pulmonary disease ^b	10 (11.5)	4 (7.0)	6 (20.0)
Rheumatic illnesses ^b	8 (9.2)	4 (7.0)	4 (13.3)
Thrombosis, embolism ^b	3 (3.5)	2 (3.5)	1 (3.3)
Epilepsy ^b	1 (1.2)	0 (0)	1 (3.3)
Thyroid disease ^b	16 (18.4)	10 (17.5)	6 (20.0)
Serious injury in the past ^b	13 (14.9)	7 (12.3)	6 (20.0)
Operation in the last 6 months ^b	13 (14.9)	7 (12.3)	5 (16.7)
Allergies ^b	26 (29.9)	14 (24.6)	12 (40.0)
Social factors			
Living alone ^b	46 (52.9)	32 (56.1)	14 (46.7)
Assisted living ^b	36 (41.4)	24 (42.1)	12 (40.0)
Education ^e	32 (36.8)	20 (35.1)	12 (40.0)
Medical treatment			
Current medication intake ^b	74 (85.1)	50 (87.7)	24 (80.0)
Current medical treatment ^b	40 (46.0)	25 (43.9)	14 (46.7)
Oxygen unit ^b	2 (2.27)	1 (1.7)	1 (3.3)

Notes: ^aFollowing the graduated step index; ^bstated: yes/no; ^cDemTect score 9–12; ^dDemTect score 0–8; ^eno or low school-leaving qualification.

Abbreviations: CG, control group; GESTALT, GEhen, Spielen und Tanzen Als Lebenslange Tätigkeiten [walking, playing and dancing as lifelong activities]; IG, intervention group.

group, the largest shifts from T0 to T1 appeared from “low activity” to “somewhat active” or “active” and from T1 to T2, it was the other way around. In the control group, there was no such tendency.

Figure 3 shows the results of mean step counts for each prevention provider and group. Particularly striking here

are, above all, the very different initial levels of PA between the groups. Participants from provider 3 had a very high initial level with an average of 8,290 steps at baseline. On the other hand, participants from provider 5 had a comparatively much lower initial level with around 2,490 steps on average. Three out of five intervention groups (providers 1, 3

Table 5 Primary and secondary outcomes by group at baseline, 3 and 12 months

Outcome	Intervention group mean (SD)			Control group mean (SD)		
	Baseline	3 months	12 months	Baseline	3 months	12 months
Steps (n=79)	5,398 (±2,821)	6,783 (±2,685)	6,042 (±2,619)	4,537 (±2,719)	4,868 (±2,085)	4,929 (±2,545)
Cognitive functions (n=82)	15.68 (±2.64)	15.83 (±2.65)	16.78 (±1.74)	14.71 (±2.59)	15.68 (±2.25)	16.21 (±1.93)
Social activity (n=82)	2.51 (±1.01)	2.68 (±1.13)	2.93 (±0.83)	2.74 (±1.08)	3.20 (±0.89)	2.86 (±1.22)

Table 6 Time and between-group effects at 3 and 12 months after baseline assessment

Outcome	Time	Intervention group	Control group	Between-group difference (group × time)		
		(time effect)	(time effect)	Difference of mean changes (95% CI)	Effective size Cohen (d)	p-value
		Mean change (95% CI)	Mean change (95% CI)			
Steps (n=79)	T0-T1	940.8* (436.0, 1,445.7)	74.4 (-653.3, 802.1)	866.4 (-19.2, 1,752.1)	0.438	0.055
	T1-T2	-1,018.3* (-1,544.9, -491.8)	-152.3 (-889.1, 584.6)	-866.0 (-1,771.7, 39.6)	-0.428	0.061
	T0-T2	-77.5 (-596.4, 441.4)	-77.9 (-806.9, 651.1)	0.4 (-894.4, 895.2)	0	0.999
Cognitive functions (n=82)	T0-T1	0.0229 (-0.5410, 0.5868)	0.8849* (0.1226, 1.6472)	-0.8620 (-1.8102, 0.0862)	-0.399	0.074
	T1-T2	0.8589* (0.2662, 1.4517)	0.2369 (-0.6141, 1.0880)	0.6220 (-0.4152, 1.6592)	0.264	0.236
	T0-T2	0.8818* (0.2839, 1.4798)	1.1218* (0.2684, 1.9753)	-0.2400 (-1.2821, 0.8021)	-0.101	0.648
Social activity (n=82)	T0-T1	0.1746 (-0.0874, 0.4366)	0.4174* (0.0498, 0.7851)	-0.2428 (-0.6943, 0.2086)	-0.236	0.288
	T1-T2	0.2137 (-0.0617, 0.4891)	-0.3324 (-0.7300, 0.0652)	0.5461* (0.0624, 1.0298)	0.496	0.027
	T0-T2	0.3883* (0.0913, 0.6853)	0.0850 (-0.3294, 0.4994)	0.3033 (-0.2066, 0.8132)	0.261	0.240

Note: *Indicates significant results in mean change.

Abbreviations: T0, baseline measurement; T1, measurement after 3 months; T2, measurement after 12 months.

and 5) showed an increase of mean steps to T1 and a similar decrease of mean steps to T2. The other two intervention groups (providers 2 and 4) also showed an increase of mean steps to T1, but then kept their PA level to T2 clearly above their initial level.

During the follow-up phase, negative life events occurred in both the groups ($n_{IG}=9$ [20.9%]; $n_{CG}=7$ [30.4%]) which completed the T2 assessment. GESTALT-kompakt participants reported fractures (n=3), operations (n=3), a slipped disc, an incisional hernia and an electric shock with a head trauma as negative events. Control group participants reported operations (n=2), endoprosthesis (n=2), an accident causing broken ribs, a stroke and syringomyelia.

Cognitive functions

After 3 months, significant improvements were observed for cognitive functions in the control group, but not in the intervention group. However, the interaction effect was not significant ($-0.86, p=0.074$). From T1 to T2, there was no significant interaction effect, but a significant increase of cognitive functions in the intervention group. There was no overall effect of the intervention over both phases because both groups had significant improvements in DemTect scores.

Social activity

After 3 months, no significant interaction effect was observed compared to the control group. There were very small time

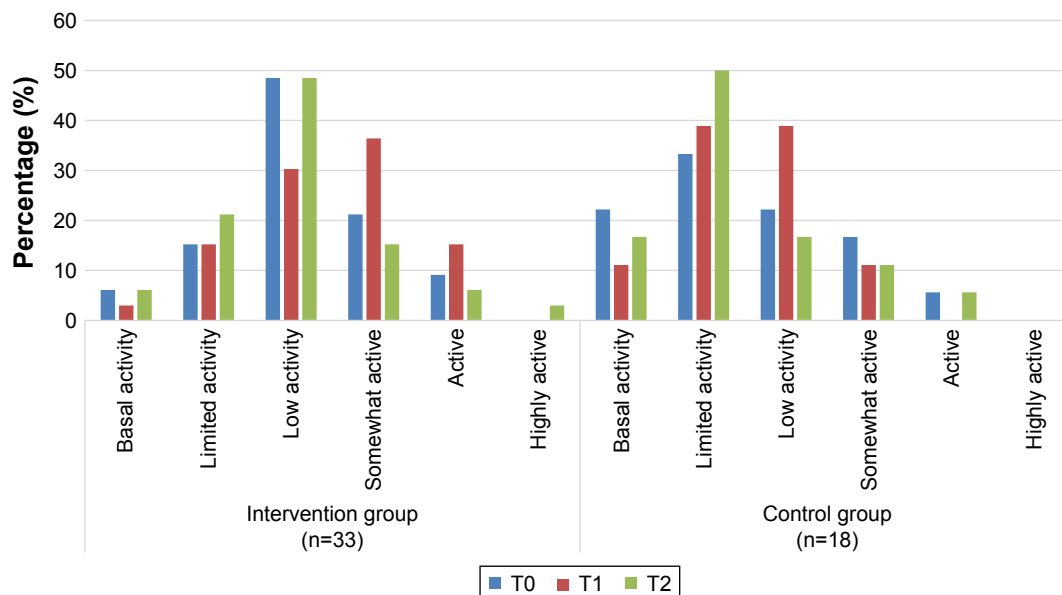


Figure 2 Assignment of mean steps to the graduated step index for both groups.

Note: This figure only includes participants who had valid results at all three points of measurement.

Abbreviations: T0, baseline measurement; T1, measurement after 3 months; T2, measurement after 12 months.

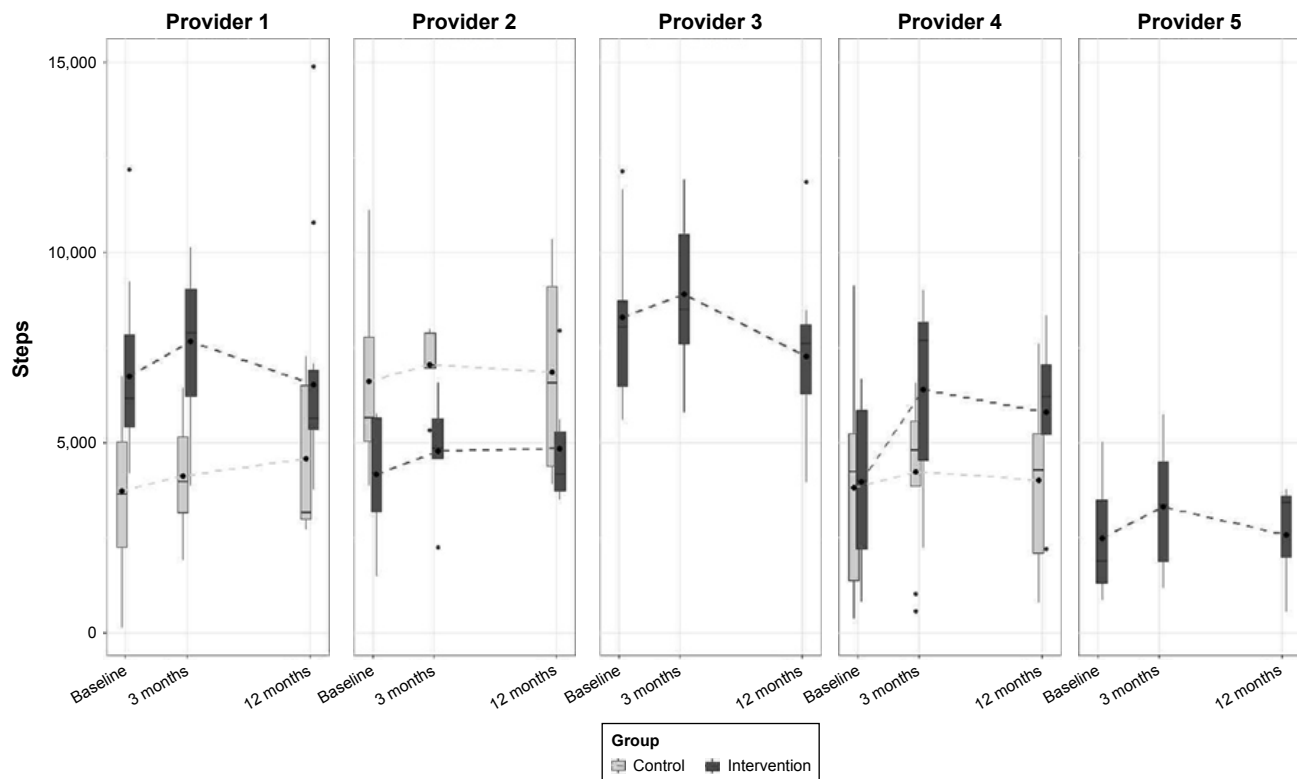


Figure 3 Boxplots of mean step counts for each provider and group.

effects after 3 months in the control group and after 12 months in the intervention group, but there was no overall intervention effect on social activities after 12 months. The baseline mean value was almost equal for the intervention and control groups. The overall mean value did slightly rise in the intervention group from T0 to T1 and again to T2. In the control group, there was a small increase to T1 and a decrease to T2. Looking at the three subscale mean scores, there were no prominent changes in either of them.

Discussion

Prevention of dementia is a public health concern and the translation of evidence-based prevention programs into the health care system is warranted. However, the effectiveness of such programs is seldom examined in real-world settings. There is growing evidence that highlights the promotion of PA and exercise because of its various beneficial effects on brain health and specific risk factors of dementia. This study assessed the short- and long-term effectiveness of a multimodal and multicomponent dementia prevention intervention in different real-world settings (in German health care) in older adults.

The multimodal GESTALT-kompakt intervention did not have effects on the PA of participants in the long term in comparison to an active unimodal control group, but it

led to marginally significant effects after 3 months in the intervention group. No effects have been observed for cognitive functions and social activities in the short term and in the long term.

GESTALT-kompakt satisfied providers and participants, which is an important prerequisite for an effective program and for successful implementation. The interest of prevention providers and instructors in GESTALT-kompakt was high. It was successfully implemented at the sites of five prevention providers in the community and assisted living setting. Recruitment strategies through various channels reached a representative group of the Bavarian population for this age group. The 57 GESTALT-kompakt participants had a high compliance to and satisfaction with the program. The dropout rate was low, which was comparable between groups and comparable to the original GESTALT program. In GESTALT-kompakt and in GESTALT, only a few participants dropped out because of the program. Noticeably, more participants of the intervention group dropped out in the setting of assisted living. This might be due to the higher age and fragility of participants in this setting.

Many modifiable and nonmodifiable risk factors have been identified in the study population. In this study cohort, participants had multiple risk factors for dementia. The same findings were observed in a previous GESTALT study,³¹

where participants had an average of four risk factors. Regarding physical inactivity as one main risk factor, GESTALT-kompakt participants improved their step counts on average by 17% from T0 to T1, which is ~900 steps/day. This increase is comparable to other pedometer-based interventions in older adults (eg, 775 steps/day).³⁹ A conspicuous aspect was the big differences in baseline steps. Participants with basal activity at baseline (<2,500 steps) had the fewest changes in mean steps/day in both groups. Participants with the highest baseline values to T0 (active and high active) suffered the highest losses in both groups. Most improvements were observed for participants with limited to low activity levels at T0 in both groups. Thus, we assume that the baseline PA level of participants might moderate the effectiveness of the study. Taking into account the intervention length, the 12-week GESTALT-kompakt program showed its effectiveness for a specific subgroup of older adults. It can be speculated that longer interventions might be a more adequate strategy to initiate and maintain PA of older adults with even lower PA levels at baseline. Considering implementation aspects, however, the shortening of the program was beneficial to better reach physically inactive persons than in GESTALT (lower entry barrier)³⁷ and fit the needs of prevention providers (funding by health insurances). Future research might be needed to strike the right balance between the two.

Considering the determinants of PA of older adults, for example, health status and motivation, the heterogeneous subgroups might require different and more personalized approaches (eg, a person with high motivation and limited health status vs a person with low motivation and good health status). A meta-analysis supports this finding, stating that PA interventions tested among healthier older adults were more effective in improving PA behavior than in chronically ill subjects.⁴⁷ The high amount of negative life events during the follow-up period should be considered for power calculations. As they occurred to a similar number of participants in both groups, they did not distort the long-term effects.

Consequently, this affects the secondary outcomes. GESTALT-kompakt did not lead to significant improvements in cognitive functions of the older adults, compared to the active control group within the study period. Both groups had high baseline values of 15.7 and 14.7 from 18.0 possible points. In both groups, there were slight increases in the mean value at all three points of measurement, whereby the control group showed slightly more increase overall. This may be explained by the lower baseline value of the control group. Participants might have become familiar with the assessment procedure.

Regarding social activity, the intervention did not lead to improvements, compared to the active control group. One reason might be that due to the new activities initiated by GESTALT-kompakt, the usual activities of participants simultaneously decreased, so that the overall quantity of social activities stayed the same. In the assisted living facility, the health status was a major barrier to taking up social activities. It is suggested that different factors at the individual, inter-individual, organizational and community levels influence if and how much the social activities change.

Strengths and limitations

The strengths of our study include a manualized, multimodal, multicomponent evidence-based PA program, a high treatment integrity according to the study protocol supported by the detailed manualized procedure and training of instructors, high compliance to and satisfaction with the program, objective measurement of PA behavior, reach of physically inactive people, successful implementation in practice, as well as public and independent funding of the study. The GESTALT-kompakt study was enriched by a high diversity of settings, providers, instructors and participants. The outcomes and measures of GESTALT-kompakt were chosen in a participatory planning process together with all stakeholders to ensure relevance.

Multicomponent and multimodal interventions – such as GESTALT-kompakt – are needed for optimum effects in dementia prevention.⁴⁸ Nevertheless, this involves challenges regarding study design and measures. The given financial and personnel conditions of the study allowed a controlled design with three points of measurement. To get more conclusive results and to learn exactly how the intervention influences physical, cognitive and social activity behavior of participants, a single-case experimental design with repeated measurements offers a considerable option. When participants are only measured before and after the study, the typical pattern of natural fluctuation of the variables is often unknown, making it difficult to distinguish between the natural patterns of fluctuation and a true intervention effect.

To map the complexity of dementia and its risk factors targeted by multimodal interventions, another possibility would be a statistical analysis of a composite endpoint consisting of physical, cognitive and social activities. Therefore, bigger sample sizes are needed.

Moreover, we based parts of the measures on self-report, which could be influenced by response bias. The objective measurement of physical activities by pedometer could have

been influenced by increased motivation to be active through wearing the device at baseline. However, this counts for intervention and control groups.

The cognitive measure (DemTect) could be influenced by recall bias. To minimize this influence, two available versions of the test were used alternately. New scoring routines for people 60+ years vs 80+ years have been established for version A, but not for version B of the DemTect yet. Therefore, no adjustment to age was possible, even if the instrument has proven to be age dependent but not education dependent.⁴⁹

An economic evaluation is warranted in future studies.

Conclusion

The GESTALT-kompakt study investigated if an evidence-based multimodal program (GESTALT) which was reduced to a 12-week version has short- and long-term effectiveness compared to the standard prevention approach in Germany in real-world settings. PA is a proximal health behavior that should be an integral part of multimodal interventions because it has the potential to address several risk factors and disease mechanisms simultaneously.

Results of GESTALT-kompakt showed a considerable time effect on the primary outcome PA at T1 in the intervention group, but not on the cognitive functions and social activities of the participants. No overall effects could be measured after 12 months. Hence, we have to assume that the 12-week intervention with its methods to increase and maintain PA levels over time was too short to cause lasting changes in lifestyle and cognition. Therefore, we recommend PA programs with longer duration (>6 months) to change the behavior persistently and plea for an adaptation in German funding schemes to support this goal.

As the effectiveness of the intervention might depend on the individual initial levels of PA, cognitive functions and social activities before the beginning of the program, some participants might profit more from the multimodal approach of GESTALT-kompakt than others do. The heterogeneous subgroups within the older adults (eg, very inactive and limited health status) might require different and even more personalized approaches.

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Disclosure

The authors report no conflicts of interest in this work.

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