

BaSAIt — A mixed-methods study protocol on setting-based physical activity promotion and counseling in nursing homes

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ABSTRACT

Introduction: Physical activity (PA) is a major contributor to healthy aging. However, physical inactivity is prevalent among the elderly in Germany, particularly in institutionalized settings such as nursing homes. This paper aims to describe the study objectives, design, methods, assessment types, collection schedules and considerations for analyzing the data within the BaSAIt study on facilitators and barriers for PA promotion in nursing homes.

Methods: We designed the BaSAIt study as a participatory intervention study with multiple measurement points in six to eight nursing homes with a total of approx. 200 residents using four main modules: (1) setting-level analysis of physical activity patterns, physical activity-related climate and physical activity-related interaction with ‘significant others,’ and organizational facilitators and barriers to physical activity, (2) physical-activity related individual-level analysis of objective and self-reported physical activity and sedentary behavior, a geriatric assessment with established procedures, assessment of people’s activity and health biographies (biographical mapping) as well as their motivational, subjective well-being and distress status, and (3) a counseling module that integrates counseling at the setting level as well as individual physical activity counseling for residents. In module (4) evaluation, the effects of integrated counseling with regard to the implementation of PA promotion strategies are analyzed.

Discussion: This study will extend our knowledge of physical activity promotion in German nursing homes. Its findings will inform governmental authorities, care professionals, and academics on how to reach a particular group, characterized by inactivity, multimorbidity, and a high prevalence of dementia, residing in nursing homes, a setting that will gain further relevance in the future.

1. Introduction

According to the current prognosis, the German population aged 65 years and older will rise from 17.3 million at present to 23.7 million by 2060 [1]. Maintaining the health of the older population will thus become one of the most important health policy tasks. To maintain the health of an aging population, physical activity promotion appears particularly important [2].

Chronic diseases, such as cardiovascular diseases, strokes, high blood pressure, type II diabetes, dementia, depression, as well as excessive weight gain, loss of autonomy in ADLs, falls in older people, and

various types of cancer could be prevented or their treatment could be supported through regular physical activity [2]. Regularly physically active older people are biologically younger, present with fewer chronic illnesses, less depression and less severe mobility impairments, and display a higher activity and health-related self-efficacy than inactive older people [3]. Inactive older people, however, are rather the norm than the exception.

The German DEGS1 study found that only 11% of women and 17% of men aged 70–79 years engage in sufficient PA to meet the A guidelines of the World Health Organization WHO [4]. In addition, the proportion of time spent sitting daily increases continuously with age, from

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55% (7.7 h) among people aged 20–29 years to 67% (9.6 h) in people aged 70–79 years [5]. However, these studies do not differentiate the contexts older people live in, whether they live independently or in nursing homes.

A study conducted in German nursing homes by Cramer-Ebner et al. [9] found that 44% of the residents reported they regularly went for walks, and 22% reported independently performed gymnastics exercises. 44% of the residents also stated that they regularly took part in weekly group exercise trainings and approx. One-third of the residents received physiotherapeutic treatments.

These findings indicate that exercise in nursing homes is generally regarded as relevant. However, it is doubtful whether objective measures would replicate PA levels as found by Cramer-Ebner et al. [9] and whether they are sufficient to achieve sustainable health effects among nursing home residents. Some studies analyzed the development of older people's physical status in nursing homes by measuring handgrip-strength, the associated ability to perform everyday instrumental activities, or walking speed as a central predictor of the survival probability of older people (cf. [8]). These studies show that residents' physical performance significantly and rapidly deteriorated after relocating to nursing homes [6,7].

Given the important role physical activity plays regarding physical functioning, morbidity, and survival probability, the reasons for inadequate levels of physical activity need to be understood and explained. Since personal, interpersonal, and environmental factors for PA interrelate [10], the “German National Recommendations for Physical Activity and Physical Activity Promotion” support multi-component approaches to the promotion of physical activity among older adults [11]. Such approaches include PA programs, the design of PA-friendly infrastructures and social environments as well as individual PA counseling. For older adults, individual PA counseling and courses that take into account their socio-spatial contexts are recommended [11]. To successfully promote PA in nursing homes, it is hence not sufficient to consider primarily individual-focused strategies to promote the PA levels of older adults. Attention should be paid to the same extent to the socio-spatial contexts of older adults, more specifically the structural contexts they live in, with regard both to concrete infrastructures and organizational-institutional set-ups. In addition, the mediating and multiplier effects stemming from the behavior of the increasingly older, health-impaired, and culturally diverse staff of the institutions themselves must be taken into account. The extent to which caregivers promote physical activity among residents, however, has not yet been investigated. It can be assumed that the promotion of physical activity by caregivers depends firstly on subjectively available time, secondly on their knowledge of how to organize physical activity with health effects, thirdly on their relationship to physical activity (previous experience of PA, PA motivation), fourthly on their own physical health, and fifthly on the fear of liability in the event of a fall or injury. Furthermore, the influence of visitors (as significant others) on the extent of residents' everyday PA must be taken into account.

1.1. Research aims and questions

This study protocol aims to describe the study objectives, design, methods, assessment types, collection schedules, and considerations for analyzing the data within the BaSAlt study on facilitators and barriers for PA promotion in nursing homes.

1.2. The BaSAlt study has two aims

- (1) To generate knowledge about the structural and personal conditions of older adults' PA in nursing homes. An extensive analysis of current PA behavior among nursing home residents is the prerequisite herein to explore factors that promote or hinder the implementation of PA promotion actions.

The main research questions here are:

- What are the structural conditions of older adults' PA in nursing homes?
 - Which factors are considered as promoting or inhibiting the successful implementation of strategies to promote PA in nursing homes?
 - What are the individual conditions of older adults' PA in nursing homes?
- (2) To develop an integrated counseling approach based on the gained knowledge that addresses both the setting and the individual level of PA promotion in nursing homes.

The main research questions here are:

- What should an integrated counseling concept that aims to improve residents' PA behavior by addressing their social and structural environment contain
- How can employees (multipliers) and residents be involved in the participatory process of analysis and counseling?
- Which PA-promoting activities are considered useful and feasible?
- To what extent does counseling create a PA-friendly climate and setup in nursing homes?

2. Methods

We designed the BaSAlt study as a participatory intervention study with a mixed-methods evaluation approach in selected nursing homes in Southwestern Germany. The collected data will be used to develop and evaluate an integrated approach for the promotion of physical activity combining setting-oriented and individual counseling. The study started in June 2019 and will last until December 2022. It is funded by the Physical Activity Research Program of the German Federal Ministry of Health (grant No. ZMVI1-2519FSB114).

2.1. Study setting and participants

The study will include six to eight nursing homes with a total of approx. 200 residents. We will apply purposive, pragmatic sampling of nursing homes that vary regarding their environmental contexts (urban and rural), responsible bodies (different non-profit institutions), and organization forms, as well as capacities and compositions of resident populations. We will exclude for-profit institutions and institutions with only bedridden residents. The study concept and design will be presented to the nursing home managements during a team meeting. Their inclusion will depend on their interest in participating and their compatibility with the overall sample requirements.

Inclusion criteria for the individual-level assessment are a max. Level of care that equals 4 (out of 5) in the German healthcare system and the motivation to participate. Exclusion criteria are levels of care of 5. Participation is voluntary and all participants (or their official legal caregivers) will provide written informed consent for participation.

3. Methodological approach

The following Fig. 1 summarizes the participatory intervention study's methodological approach in the four modules [1] setting-level (pre-) analysis [2], individual-level PA-related (pre-) assessment [3], counseling, both setting-oriented and individual-related, and [4] process- and (post-)evaluation.

Table 1 (below) provides a detailed overview of the assessment methods, instruments, and measurement points in BaSAlt. T1 stands for the pre-assessment period, T2 for the second assessment immediately before the start of the individual counseling and the implementation of the actions developed in the setting-specific counseling, T3 stands for

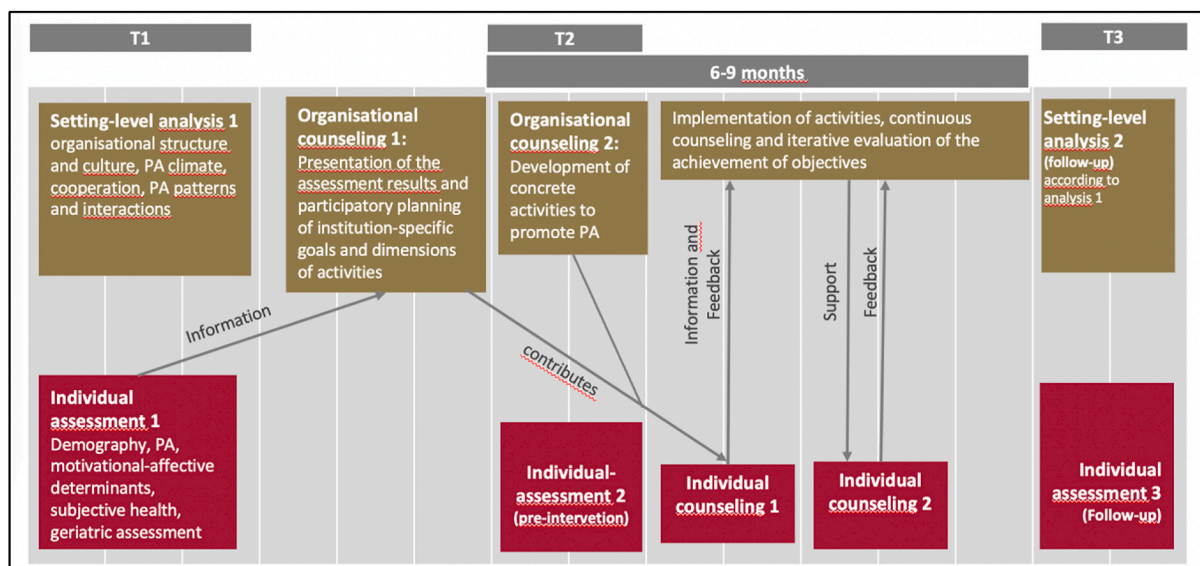


Fig. 1. Schematic Overview of the BaSAlt study modules over time, for one nursing home.

the third assessment six months after the start of the counseling process in the respective nursing home.

We will conduct a setting-level analysis to assess facilitators and barriers to PA as well as organizational readiness for PA promotion. Furthermore, patterns and dynamics of everyday PA and the PA climate in the participating nursing homes will be examined. We designed the setting-level analysis in a mixed methods design (cf. Table 1). The analysis includes structured on-site observations and sensor-based assessments (GAITrite® system) [12] of PA patterns and interactions as well as PA-related infrastructure audits of the nursing homes. We will conduct photovoice documentations by residents, staff, and visitors identifying options for and barriers to PA in the nursing homes ($n = 6$ participants per nursing home). We will conduct semi-structured qualitative interviews ($n = 3$ per nursing home), focus groups ($n = 1$ per nursing home), online-based questionnaires with staff and visitors (Physical Activity Scale for the Elderly PACE [23] and PASE [24]), and document analyses to assess PA climate, structure, and culture in the nursing homes.

We will also conduct an individual-level PA-related assessment with residents in each of the participating nursing homes.

To assess the residents' individual physical activity behavior, we use accelerometer-based devices (ActiGraph wGT3x-BT, Pensacola, FL). We record residents' total physical activity in everyday life over seven consecutive days, including weekdays and weekends.

The selection of the primary outcome measure regarding accelerometry and the positioning of the ActiGraph devices was made with particular consideration of older adults living in nursing homes. It is important to note that the participants may have a very slow and asymmetric gait caused by age-related mobility limitations or various diseases (e.g., post-stroke-period, neurological diseases). For activity recording with accelerometer-based devices, some studies examining these gait conditions have indicated that the ankle position offers advantages regarding adequate measurement when compared to the more common waist position (Anderson et al., 2019; Campos et al., 2018; Gorzelniak et al., 2012). For example, the use of ankle-mounted ActiGraph devices has demonstrated validity and reliability for quantifying step counts in older adults with various diseases associated with slow walking speed (Anderson et al., 2018; Webber & St. John, 2016).

Hence, concerning the primary outcome of our accelerometric measurements, we decided to use steps-per-day recorded via ankle-mounted ActiGraph devices. For additional secondary analyses, minutes per day with sedentary behavior as well as with physical activities

of light, moderate, and strenuous intensities will be considered. Only those days will be included in the analyses in which at least 10 h of wearing time can be registered, so that valid information about the total activity per day can be assumed. Accordingly, no adjustment will be made for wear time. As a result, more weight is given to the actual activity recorded, regardless of the wearing time, than to the risk of missing physical activities during non-wear-time.

Using interview-administered questionnaires (cf. Table 1), we will gather information on self-reported physical activity (PASE or PASIPD, option for wheelchair users as well as individual's activity prerequisites with regard to exercise participation motives (Bernese motive and goal inventory; BMZI (adapted version), exercise-specific self-efficacy (SEES adapted version), and activity restriction due to fear of falling (adapted version). Additionally, the questionnaire includes subjective health indicators (see Table 1, WHO-five Well-Being Index; European Quality of Life 5 Dimensions 3 Level Version; EQ-5D-3L), which comprise subjective well-being and health-related quality of life. Further self-reports on residents' former participation and future interest in structured PA offers and other socially triggered physical activities will be collected by way of interview-administered questionnaires.

In addition, we will conduct a sarcopenia screening according to the European Working Group on Sarcopenia in Older People 2 (EWGSOP2) [13] of the participants. For this purpose, standardized tests are implemented according to the given algorithm for the quantification of sarcopenia. These tests serve to determine muscle strength, muscle mass, and physical functioning. Furthermore, the participants' nutritional status will be assessed via a nutrition questionnaire [14,15].

In a selected sub-sample of residents we will conduct a retrospective activity mapping for T3 [16]. The mapping is intended to assess residents' subjective perspective on their physical activity experience during the intervention.

Due to the COVID-19 pandemic and its restrictions since March 2020, we have trained nursing staff to conduct a basic set of assessments (indicated in Table 1). As a consequence the instruments had to be reduced to allow assessments to be executed by nursing staff in the homes. For example, we had to dispense applying a standardized physical activity questionnaire and decided to focus our physical activity assessment on a combination of accelerometry and interview-administered questions on structured physical activity offers.

Table 1
Overview of assessment domains, methods, and instruments in BaSAlt Setting-level analysis.

| Measurement points | | T1 | T2 | T3 |
|---|---|----|----|-----|
| PA patterns and interactions | Systematic guideline-based observation [17–20] | x | | (x) |
| | Ethnographic field notes | x | | |
| | Sensor-based assessment of PA patterns (GAITRite®) [12] | x | x | x |
| PA-related organizational structure and culture | Semi-structured qualitative interviews (executive staff) | x | | |
| | Focus groups on options and barriers for PA | x | | |
| | Document analysis (mission statement, care concept etc.) | x | | x |
| | Infrastructure audit; adapted from S-SCEAM und EIM | x | | x |
| PA climate | Ethnographic field notes | x | | |
| | Semi-structured qualitative interviews (executive staff, staff) | x | | |
| | Photovoice Documentation | x | | |
| | Survey study (staff, significant others, external service providers); PACE [21] and PASE [22] | x | | |
| | Ethnographic field notes | x | | |
| Individual Assessment: physical activity, motivational-affective PA determinants and subjective health status | Process and outcome evaluation workshop | | | x |
| Demographic data | Demographic questionnaire | x | x | x |
| Physical Activity | Accelerometry (ActiGraph, Pensacola, FL) | x | x | x |
| | Former participation and future interest in structured physical activity offers and socially triggered activities | x | x | x |
| | Retrospective activity mapping [16] | | | x |
| Activity restriction due to fear of falling | Single-Item-Scale (24, adapted version) | x | x | x |
| Motivation | Bernese motive and goal inventory; BMZI ([25], adapted version) | | x | x |
| Self-Efficacy | Self-Efficacy for Exercise Scale; SEES ([26], adapted version) | x | x | x |
| Well-Being | WHO-5 Well-Being Index [27] | x | x | x |
| Health-related quality of life | European Quality of Life 5 Dimensions 3 Level Version*; EQ-5D-3L [28] | x | x | x |
| Geriatric Assessment | | | | |
| Demographic data and morbidity status | Age, sex, degree of care, number of falls, weight loss, and recording of diseases in categories (inspection of patient files) | x | x | x |
| Anthropometric data | Size (in m), weight (in kg), and BMI (in kg/m ²) | x | x | x |
| Body composition | Bioelectrical impedance analysis (impedance vector analyzer BIA 101 BIVA, SMT medical, Germany), measurement of ASMM (in kg) and SMI (in kg/m ²) [29] | x | x | x |
| Handgrip strength | Dynamometer (hydraulic hand force dynamometer SH5001, Saehan, Korea), maximum hand force by isometric test (in kg) [30] | x | x | x |
| Physical functioning | Short Physical Performance Battery; SPPB, walking speed over 4 m walking distance (in m/s) [31] | x | x | x |
| Cognition | Mini-Mental State Examination; MMSE [32,33] | x | x | x |
| Activities of daily living | Barthel Index [34] | x | x | x |
| Subjective sarcopenia | Questionnaire for subjective self-assessment to determine sarcopenia; SARC-F [35] | x | x | x |
| Nutrition status | Mini Nutritional Assessment; MNA-SF®, subjective assessment to determine malnutrition [36] | x | x | x |

3.1. BaSAlt intervention — integrated counseling

A total of approx. nine months are dedicated for counseling on how to implement PA promotion in the institutions. The aim of the intervention is to provide the institutions with the necessary knowledge and skills for the independent implementation of both structural and behavior-related activities and actions.

The BaSAlt study intervention consists of an integrated counseling approach, the counseling module. The counseling module will feed the results of the setting-level analysis and of the individual-level assessments back into the nursing homes.

A series of *participatory future workshops* [37,38] in each institution will form the central basis for the counseling module. Research partners, representatives of the management level, employees, residents, and visitors/relatives will jointly define goals at the structural and individual level, groups to be addressed, and goal achievement scales for their institution (cf. [39]). The participation in *future workshops* is organized by each institution and attendance is voluntary.

During the *future workshops*, we will provide recommendations for promoting physical activity based on the findings from the assessment modules. If necessary, we will also provide recommendations on how staff could be qualified in the area of physical activity promotion. Such a qualification might be achieved via the establishment of a PA promotion certification, in cooperation with participating partners such as the major regional health insurance company. Recommendations might also refer to a more PA-friendly design of organizational processes, such as the coordination of shift plans and PA offers by the occupational health management, and the specific qualification of those responsible for PA courses for residents (e.g. further qualification as a trainer for older adults within the German organized sport system), but also the development of PA expertise among those responsible for quality management or worksite health promotion in the respective institutions. The setting- and organizational-level consultation will also include recommendations on existing and evaluated PA courses and programs that might be appropriate for the health promotion of older people in elderly care homes (cf. [40,41]). If necessary, the programs will be adjusted to existing structures and competencies to initiate local cooperation opportunities (e.g. sports clubs).

Based on the researchers' presentation of the assessment modules' results for the respective nursing home, participants of the *future workshops* will discuss implementation options and barriers, select or develop concrete actions for their respective institutions, and initiate their implementation. To promote sustainability and institutionalization on-site, the implementation of planned actions is the responsibility of the respective institution, advised and supported by the scientific project partners. To support institutions in the implementation of PA-promoting infrastructures and programs, each institution will receive a budget (up to EUR 10.000) as seed money for the implementation of planned actions, once the *future workshops* have been conducted.

As part of the intervention, a submodule for individual-level PA counseling of residents will be offered to the nursing homes and their residents. The individual-level PA counseling will only be provided for residents who have given written informed consent. Due to the dynamics in the setting and the environmental conditions in the specific nursing homes, individual counseling may be delivered personally or as web-based video counseling, in both cases by trained research staff from the BaSAlt project team. Individual counseling will be structured in accordance with the 5 A concept [42,43]. This concept describes a process consisting of diagnosis (assess), recommendation (advise) and agreement of goals (agree), support in changing behavior (assist), and arranging follow-up meetings (arrange). Information from the individual-level PA-related assessment module serves as basis for the first counseling session, in which personal activity goals are agreed upon that consider individual needs and the social-infrastructure conditions in the nursing home (e.g. type and frequency of participation in PA pro-

grams, targeted self-training or strategies for integrating physical activity into everyday life). Furthermore, behavior change techniques are applied to support the achievement of this goal (e.g., action plans and coping plans). In one or two shorter refresher sessions goal attainment is evaluated according to the requirements, and handling barriers to achieving a goal is addressed.

4. Evaluation

In the **evaluation module** we will conduct post-evaluation in each nursing home. We will monitor the implementation of the setting-level and individual-level objectives developed in the institutions and evaluate the effects of the implemented actions six months after the start of the counseling module. Post-evaluation will build upon the methods and instruments for the setting- and individual-level analyses from the first two BaSAlt modules (cf. [Table 1](#) on T3 post-assessments). At the setting level, the evaluation of the actions and implementations following the counseling module can be classified as complex [44,45]. Firstly, the participatory approach of organizational analysis and consulting asks for flexible rather than predefined intervention designs. Secondly, we expect a variety of interactions between the different BaSAlt project components, in particular between organizational counseling and individual counseling. This variety cannot be pre-defined a priori. Thirdly, we expect an interaction between the intervention's components the relevant actors, and the structural conditions in the specific settings. It is therefore important for the evaluation process to systematically document and prepare both the PA-relevant structures in the institutions and the processes that can be observed while counseling on implementation in detail. It is also important to develop a gradual differentiation of implementation quality, i.e. ideas of a "better" or "worse" implementation of proposed actions (cf. [46]). Such differentiation allows for a comprehensible evaluation of change processes on an organizational and individual level and thus substantially supports the interpretation of effects on PA behavior.

To do so, we will use selected measurements from T1, the setting-level analysis, to measure changes in PA patterns and interactions, PA-related organizational structure and culture, as well as the PA climate in the nursing homes. We will also conduct participatory evaluation by employing goal attainment scaling [47] to evaluate the implementation and success of actions together with the counseling module participants during an evaluation workshop.

At the individual-level assessment, changes within subjects are measured at three points by the described individual assessment procedures. With regard to stepped wedge designs [47], there will not yet have been any implementation of interventions between the first (T1) and second assessment (T2), hence the period will be considered a control phase. As the second measurement will take place before the start of the counseling module, the subsequent period between T2 and T3 will be mainly influenced by the participatory intervention for the promotion of PA.

The longitudinal observations will allow for the assessment of individual changes in the behavioral, motor, and psychological characteristics of the participating residents in the course of the study. Thus, relations between changes in organizational as well as individual activity features and individual functional capacity and subjective health can be analyzed. In addition, comparable indicators of the geriatric comprehensive assessments from the Baden-Württemberg KODAS [48,49] data will be used as an external reference. These comparisons will make it possible to contextualize time- and disease-specific distortions of the results.

5. Discussion

PA provides a key resource for healthy aging in seniors beyond 65 years. Sufficient PA levels might prevent functional decline and the

progress of chronic diseases. However, broader evidence is needed regarding structures and strategies promising PA promotion in relevant settings, such as nursing homes. The BaSAlt study aims to contribute to such an increased evidence base.

The strength of the study lies in its application of a setting-based real-world approach to researching and promoting PA in nursing homes. As one of the first studies BaSAlt combines setting-level and individual-level PA counseling. This combination allows us to analyze the potential effects and benefits of different strategies in a growing and relevant sector for health promotion through PA in aging populations.

One limitation of this study is time restriction. Educating and obtaining informed consent will be more time-consuming than for studies in a younger population, as caregivers may be involved. Residents will experience age- and disease-related limitations that will place them at higher levels of care, and some subjects may even pass away during the study period. This risk of an increased dropout-rate is countered and controlled by the stepped wedge waiting-design and two points of assessment T1 and T2, with no intervention taking place between said assessment periods. To ensure the sustainable recruitment of participants, the project and evaluation designs follow a real-life approach.

The participatory paradigm of our study should allow that potential reservations on the part of managers, employees, and relatives (e.g. concerning increased risk of falls during mobilization activities, liability issues, etc.), as well as existing structural barriers for promoting physical activity in the settings (e.g. lack of personnel or lack of physical activity expertise), be targeted from the onset. Hence, the semi-structured qualitative interviews conducted as part of the setting-level analysis and on-the-spot observations can provide information on PA barriers and potentials but may also allow to address and overcome these barriers later on during the integrated counseling process.

In general, the setting analysis and counseling process in the participating institutions will provide increased knowledge on the potentials and challenges of PA promotion in nursing homes and will help to identify promising approaches for this setting and set directions for future research with the subgroups most in need in this setting.

6. Ethics and dissemination

Ethical approval for the study was granted by the Ethics Committee of the Faculty of Economics and Social Sciences at Eberhard Karls University Tübingen in July 2019 (No. AZ A2.5.4-096_aa). Amendments were granted by the Ethics Committee to acknowledge adaptations of the study design (assessment procedure and instruments, inclusion of digital elements in assessments and counseling, and safety measures to minimize the risk of spreading COVID-19) in 2020.

The collection and storage of personal data take place in accordance with the European Data Protection Basic Regulation (DSGVO) and in coordination with the data protection officers of the institutions involved. Data is treated confidentially and processed pseudonymously. All participants receive written and oral information about the study. All study participants will give informed written consent for the use of their data. If participants are not able to give informed consent themselves, legal guardians will be asked for informed written consent. Participation in the project is voluntary and can be refused, revoked, or terminated prematurely without stating reasons and without consecutive disadvantages. Adverse events will be reported to the ethics committee and any updates to the study will require the ethics committee's approval.

Our dissemination and sustainability strategy consists of multiple activities. Firstly, our participatory study design considers nursing homes as partners and experts in developing PA-promoting actions that suit their needs and increase the probability of implementation and sustainability at an organizational level. Secondly, we will give feedback on results from BaSAlt throughout the project lifetime to the governing bodies of the participating nursing homes as well as to regional care in-

insurance companies to initiate a scaling-up process for further nursing homes. We will support this attempt by developing a manual on how to promote PA in nursing homes as one of the project's products and sharing it with project partners and advisory board members from research and practice. Additionally, we will present the results to the scientific community to add to the discourse on physical activity promotion in later life (publications in peer-reviewed journals, conference presentations, etc.). Finally, dissemination to the broader public will take place via the project website (<https://www.uni-tuebingen.de/basalt>) as well as public events.

Author contributions

All authors contributed to the overall design of the study and contributed to drafts of the manuscript. AT, GS, and AF drafted the manuscript and coordinated the development of the project. AT, DA, and AF designed the protocol for the setting-level analysis and counseling. AN and DH designed the sarcopenia screening and geriatric assessment protocol and GWE contributed to the designed protocol. RP, JS, and GS designed the individual counseling protocol. All authors have read and approved the draft of the final manuscript.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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