Bridging barriers to health promotion – A feasibility pilot study of the ‘Promoting Aging Migrants’ Capabilities study’

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ABSTRACT

Rationale, aims and objectives: Improving the possibilities for ageing persons to take control over their health is an increasingly important public health issue, and health promotion has previously been visualised to succeed with this goal. However, health promotion research has primarily focused on ageing persons who are native-born, leaving the generalizability to persons who are foreign-born unexplored. Therefore, as part of the development of a randomised controlled health promotion trial for ageing persons who have experienced migration, this pilot study aimed to assess the feasibility of an adapted randomised controlled trial protocol. The specific feasibility objectives were to assess: recruitment procedure, retention rates, study questionnaire administration and variability of collected data.

Method: Forty persons who were \( \geq 70 \) years, and who had migrated from Finland, Bosnia and Herzegovina, Croatia, Montenegro or Serbia to Sweden were randomly allocated to a health promotion programme or a control group. The programme was linguistically adapted with regard to translated information material and bilingual health professionals and evaluators, and a person-centred approach was applied to both programme development and provision. The data analysis was explorative and descriptive. Results: Answering to six feasibility goals, the results visualised structural and linguistic barriers to recruitment and study questionnaire administration, and provide suggested strategies for how to bridge them. The retention rates and data variability of the programme were satisfying. Conclusions: Calling for iterative and pragmatic programme development, implementation, and evaluation, the findings provide suggestions for feasible health promotion that aims to contribute to a more inclusive healthcare environment. Person-centred, and bilingual approaches with attention to the possibilities for building authentic relationships between participants and providers are emphasised, and the findings suggest a structured methodology when developing study questionnaires.
INTRODUCTION

Providing high quality and safe healthcare requires articulated vision and clear goals for how to ensure appropriate use of resources (1, 2). However, despite increased survival and international migration rates (3), there has been little attention towards how healthcare inequities associated with ageing and migration can be diminished. Previous research with ageing persons who are born abroad have to a great extent been conducted from a poor health perspective, with focus on risk factors for disability and disease (4-8). This has led to a visualisation of this part of the population as a group with small possibilities to achieve their desired state of health across the ageing process (9).

Answering to the multidimensionality of health in the context of ageing persons, Swedish research has rendered the evidence-based program, ‘Elderly persons in the risk zone’ (10), which aims to promote the health of ageing persons. It has been proven to have statistically significant impact on health related outcomes associated with frailty (activities of daily living, self-rated health, satisfaction with health) for persons 80 years of age or older (11, 12). Frailty involves vulnerability to several different outcomes and a reduced reserve resistance to stressors in life due to a cumulative decline of multiple physiological functions (13). For the aim of this study, frailty was measured by the following outcome measures, which are associated with biological ageing: weakness, fatigue, weight loss, low physical activity, poor balance, slow gait speed, impaired cognition (10). Since ageing persons who have experienced migration commonly have been described as a group of people who are prone to develop poor health and frailty (4-8), the evidence-based health promotion programme (10) was considered a promising method to explore within a migration context.

Health promotion involves strategic measures, which aim to improve the possibilities for the whole population to take control over their health (14), and it has for a long time been visualised to have the potential to improve both health across the ageing process and lead to economic gains (15). Yet, even if strides have been made on developing health promotion for ageing persons, they have primarily focused on native-born parts of the population, limiting the generalizability to an increasingly diverse population with regard to cultural and linguistic backgrounds. As described by Torres (16), it is, however, important to take into account the common categorization of aging persons who are born abroad as a homogeneous group, which has led to a notion of them being deviant and as having migration specific healthcare needs (16).

Attempts have been made to improve the quality of healthcare for ageing persons who have culturally and linguistically diverse backgrounds (17-19), but health promotion development and implementation, which recognises the heterogeneity of this part of the population, is still an immature research field. Therefore, a person-centred approach to health promotion was explored in this study as a means to address the heterogeneous needs of the target population.
Person-centredness has a philosophical foundation in the view of all human beings as capable persons (20). A person-centred approach to healthcare consequently involves an ethical standpoint, which put high value in human interaction, and the capability people have to take control over, and influence their own healthcare process by narrating who they are and what they are capable of doing. Entailing shared decision-making; a person-centred approach to healthcare also means that all decisions with regard to the healthcare process are taken in partnerships between the person who is seeking care, and the person who is providing it (20-22).

With the aim to increase the possibilities for all persons to age in a, for them, optimal way, this pilot study is part of a larger person-centred health promotion project in a mid-sized city in Sweden, targeting ageing persons who are born abroad. An adaptive trial design (23) was applied, with the previously mentioned evidence-based programme (10) as a standpoint. The aim was to assess the feasibility of an adapted randomised controlled trial protocol, in order to improve its quality in relation to ageing persons who are born abroad. The adapted programme targets persons from the largest groups of ageing persons who have migrated to Sweden, i.e. persons from Bosnia and Herzegovina, Croatia, Montenegro, Serbia (henceforth referred to as the Balkan Peninsula), and Finland (24). With consideration to individual experiences, living conditions, preferences and desideratum that might influence different persons’ responses to healthcare interventions, the findings will guide the proceeding design and conduct of a randomised controlled trial (RCT).

METHODS
Deploying an explorative randomised controlled design and descriptive feasibility approach the evidence-based health promotion programme (10) was adapted and assessed for feasibility. Participants were recruited and randomised to the adapted health promotion programme or an inert control group. The study design was guided by the Medical Research council guidance for developing and evaluating complex interventions (25), and Thabane et al.’s (23), tutorial for pilot studies, with cautious attention to the context in which the programme took place. For further information on data, participants, study questionnaires or study protocol please contact the corresponding author.

The evidence-based programme (original protocol)
The evidence-based health promotion programme (10) was provided in a high-income suburban district of a mid-sized city in Sweden. The aim was to test if health promotion for ageing persons could prevent or delay deterioration in daily activities and health. Eligible to participate were persons who were at risk of developing frailty, which means: community-dwelling, 80 years of age or older, independent on another person in activities of daily living, cognitively intact (a score of 25 or higher on the Mini Mental State Examination (MMSE (26))).
Health promotion programme

The original protocol applied a three-armed design, with participants being randomised into senior meetings, preventive home visit or control (10).

The senior meetings were held weekly over a four-week period, and there were a maximum of six participants per group. An operative group with registered occupational therapists, physiotherapists, nurses, and qualified social workers were hired to operate the senior meetings (one professional per senior meeting). The main purpose of the senior meetings was to provide an arena for peer learning and discussions on different tools for health promotion in everyday life during the ageing process. A booklet (27) with information on self-management of health, and supportive activities available for ageing persons in the community was used as a foundation for all four senior meetings. The booklet referred to relevant topics for health and ageing in Sweden, and served as a means for preparation, and foundation for discussions to come. Throughout the programme, the professionals did however strive for a person-centred approach, drawing upon the participants’ own experiences from their everyday lives, and decided what health promotive actions were important to address accordingly. Approximately two to three weeks after the final senior meeting, one follow-up home visit was conducted by one of the professionals as an individual follow-up of the senior meetings (10).

The aim with the preventive home visit was made to each participant by one of the professionals from the operative group. The aim was to provide information and advice on various forms of activities, fall prevention and support for ageing persons within the community (10).

The participants in the control group did not receive any intervention, but they had access to conventional elderly care from the municipality, i.e. home-help services or home medical care based on each person’s needs (10).

Recruitment and randomisation procedures

Eligible persons were identified by receiving access to registers of persons who were ≥80 years and who lived within the study setting. Invitation letters were sent to all eligible persons, followed up by a telephone call, during which a baseline interview was set up for those who were interested in participating. During the baseline interview, a research assistant assessed the potential participants with the MMSE (26) and ADL-staircase (28) to identify those who were eligible for participation. Using a simple random sample chart, participants were then included consecutively until the intended sample size was reached (10).

Outcome measures and measurements

Primary outcome measures were: indicators of frailty (weakness, fatigue, weight loss, low physical activity, poor balance, slow gait speed, impaired cognition), performance of daily activities, and morbidity. Secondary outcome measures were:
quality of life, life satisfaction, assistive technology, accessibility, feeling of loneliness, social interaction, social support, participatory activities, falls, fear of falling, healthcare consumption, and mortality. For more information on outcome measurements see original study protocol (10).

Data collection
Data on demographical characteristics and outcome measures were collected by research assistants at baseline, and follow-up at three months, one year and two years after the health promotion programme (10).

Adapted programme (pilot protocol)
The aim of the adapted health promotion programme is to test the hypothesis from the original protocol in relation to ageing persons who have migrated to Sweden, and in a different socio-economic context (29). Allowing for modifications to the recruitment process, resources, management and scientific design, the objectives of this pilot study were: to assess the feasibility of the adapted programme, with regard to recruitment procedure, retention rates, study questionnaire administration, and variability of the collected data at baseline.

Adaptations were made to the original protocol with regard to: participants and setting, recruitment and randomisation processes, outcome measures and study questionnaires. Reference groups of ageing persons from the Balkan Peninsula and Finland were recruited from local associations in order to discuss the adaptations and implementation of the programme. Specific attention was drawn to the information material (booklet), recruitment methods, and the outcome measures. All adaptations were discussed between those reference groups, the operative group, project leaders for the research approach, and external researchers when needed. Additionally, all adaptations to the recruitment process, content of the health promotion programme, and the evaluation measurements were discussed in relation to qualitative background research (30, 31), and to the body of published RCTs available (32-39), before a final decision could be made in consensus between all parties involved.

Participants and setting
The eligibility criteria followed the original protocol, except for the following adaptations: Participants should be 70 years of age or older, and have migrated from Finland, Bosnia and Herzegovina, Croatia, Montenegro or Serbia. The age criterion was lowered following discussions with the reference groups, and in relation to previous RCTs of health promotion with ageing persons who have culturally and linguistically diverse backgrounds (32-39). With regard to the project's bilingual approach the reference groups were consulted on the inclusion of participants. Since people from the four included countries on the Balkan Peninsula have different linguistic backgrounds, a pragmatic recruitment strategy was applied in order to be able to provide the health promotion programme in the participants'
mother tongue. Hence, only people who spoke Bosnian or Serbo-Croatian were included.

The setting of the adapted health promotion programme was a different suburban district of the mid-sized city in Sweden, one with a low general income level and a large proportion of people who are born abroad. For more information on the different study settings, see table 1 (40).

<Insert Table 1 about here>

**Health promotion programme**

Since the effects from senior meetings and one follow-up home visit have been shown to be superior to the preventive home visit (11, 12), the pilot protocol applies a two-armed study design: senior meetings or control. The overarching aims of the senior meetings are the same as in the original protocol, and the control group follows the original protocol.

Drawing on the person-centred approach from the original protocol, all persons in the operative group participated in specific workshops on its philosophical, and practical implications of person-centredness (20-22). The purpose was to facilitate partnerships between the operative group and the ageing persons at all stages of development and implementation, with emphasis on how to make use of one’s resources in a living context. The suggestions from the booklet were discussed in relation to the participants’ expressed needs and desideratum, allowing them to learn from each other’s experiences and confer specific health related concerns with health professionals.

Linguistic adaptations were made to provision and health information, meaning that the participants could choose their preferred language for communication, Swedish, their mother tongue or a combination. For practical reasons, with regard to the access to bilingual health professionals and interpreters, the senior meetings were organised according to the participants’ preferred language. The booklet was professionally translated to Finnish, and Bosnian/Serbo-Croatian, and some small edits were made to the health information content, with added information on how to handle stress in everyday life.

**Recruitment and randomisation procedures**

Applying the same recruitment method as the original protocol, postal addresses and telephone numbers to eligible persons (with regard to country of birth and age) were identified from registers accessed via the operative group. Letters with translated information on the study purpose and content were sent to all eligible participants’ homes, and approximately one to two weeks following the letter, they were contacted by telephone by a research assistant who could speak their mother tongue. The telephone call aimed to provide further information on the study, and
give the potential participants an opportunity to ask questions before deciding on participating or not. All participants signed a consent form before participation.

Based on recommendations by Hertzog (41) of including approximately 40 participants in a pilot trial, 20 persons from Finland, and 20 persons from the Balkan Peninsula were recruited. The randomisation process followed a simple random sampling method and was conducted by the research assistants after the baseline interview. Opaque sealed envelopes were used to facilitate allocation concealment.

Outcome measures and measurements

The outcome measures and measurements were chosen based on the original protocol, and following discussions with the reference groups and external researchers, a selection of the outcome measures and measurements were selected for the adapted protocol (29). All outcome measures were provided in the participants’ mother tongue when required, and only professionally translated and validated questions and questionnaires were used.

For the aim of assessing the feasibility of the outcome measures with regard to the target groups, the following outcomes were tested for variability at baseline: Activities of Daily Living (primary outcome), fear of falls, loneliness, participation in leisure activities, frailty, life satisfaction, risk for depression, self-rated health, and symptoms.

Activities of Daily Living (ADL) was measured by the ADL-staircase (42, 43), which is a questionnaire used to measure independence of another person in the following ten ADL items: feeding, continence, transferring, going to the toilet, dressing, bathing, cooking, transportation, grocery shopping and cleaning. The questionnaire has been tested for validity and reliability in relation to ageing persons (44, 45), and the translated questionnaire used in this study was received from universities in the participants’ countries of birth. Following the original protocol, the item ‘continence’ was excluded since it was not considered an activity, and this adaptation is not considered to change the validity or reliability of the instrument.

Frailty was measured by the sum of eight frailty indicators: impaired cognition,
fatigue, weight loss, weakness, low physical activity, slow gait speed and visual impairment. One point was given for each frailty indicator, and more than three indicators were classified as frailty and one to two indicators as being pre-frail at risk of developing frailty (13). For details on instruments used, and cut-off values, see the original study protocol (10). Life satisfaction was measured with eight of the questions from Fugl-Meyer Lisat-11 (47). Questions on sexual life partner relations and family life were excluded based on large proportions of missing values on the evaluations of the original protocol. Risk for depression was measured with the Geriatric Depression Scale (48), which consists of 20 yes or no questions. Self-rated health was measured with the first question from RAND Short-Form-36 (49) ‘In general, would you say your health is: 1) Excellent 2) Very good 3) Good 4) Fair 5) Poor’. Symptoms were measured using The Göteborg Quality of Life Instrument (50), summarising the amount of symptoms reported for each participant.

Data collection
Bilingual research assistants conducted structured baseline interviews to collect data on demographic variables and all outcome measures. They all received training by the research group on how to administer the study questionnaires, and discussions with the research leaders were continuously held to test, enhance and maintain inter-rater reliability. The goal was to conduct the baseline interview as soon as possible after the recruitment phone call, and all interviews were conducted in the participants’ choice of language and location. For ethical reasons, by means of inclusion of eligible participants, the order of the questions and questionnaires were organised so that the ADL-staircase and MMSE were initial questions, following the demographical variables.

Feasibility goals
In relation to previous health promotion research findings with ageing persons who have culturally and linguistically diverse backgrounds (32-39) and to the findings from the evaluations of the original protocol (11, 12) six goals were used to assess the feasibility of the adapted protocol:

- Forty participants can be identified, recruited and included over a six-month period
- No more than 10% of all randomised participants will withdraw their consent
- More than half of the participants who have been randomised to health promotion will participate in at least two senior meetings
- More than half of the participants will provide complete answers to the study questions
- The time taken for administration of the study questionnaire will be feasible with regard to the target population (90-120 minutes)
- The collected data will show variability across participants
Data analysis
The analysis was explorative and descriptive, and the participants were divided by region of origin only when specific differences were identified. For demographic variables, independent t-test (age) or $\chi^2$ tests were used to assess the equivalence of the health promotion and control groups at baseline.

RESULTS
In total, 40 participants could be included in this feasibility study. They were between 71 to 85 years of age, and just about half of them were female. Most participants lived alone, had not received tertiary education, and had lived in Sweden for more than 21 years. Additionally, the majority of the participants had come to Sweden for work related reasons, or in order to find safe refuge from war. There were no statistically significant differences between the health promotion and control groups on the demographic characteristics. However, almost all participants from Finland (n=17) rated their Swedish proficiency level as good, whereas the proficiency level reported by the participants from the Balkan Peninsula was equally distributed between good (n=9) and poor (n=11). More information on the participants’ demographic characteristics can be found in table 2.

Recruitment and randomisation procedures
Failing to reach the recruitment goal, it took 10 months to recruit 40 participants from 449 eligible persons. It took two months for the participants from Finland, and ten months for the participants from the Balkan Peninsula. The main barrier to recruitment was difficulties with identifying registered telephone numbers to eligible persons, which is why 173 persons received a second letter with contact details to the operative group, with the aim to encourage them to take contact if they were interested of participating (58 from Finland and 115 from the Balkan Peninsula). However, this strategy proved to be unsuccessful, with a majority of persons never replying to the second letter.

During the recruitment period for this feasibility study, 46 participants could finally be randomised: 19 to health promotion, and 27 to control. Six participants withdrew their participation after the baseline interview, five who had been randomised to health promotion and one who had been randomised to control. More information on the recruitment and randomisation procedures can be found in figure 1.

An additional barrier to recruitment was to reach out to those who did not speak Swedish fluently. Interim adaptations were therefore made according to the project’s bilingual approach. An initial attempt with interpreters in tripartite phone calls proved to be impossible, which is why bilingual health professionals and
research assistants were hired and used for recruitment. With regard to the randomisation procedure, the amount of primary dropouts (13%) was over the feasibility goal of 10%.

**Retention rates**
With regard to the feasibility goal on retention rates, all of the participants who were randomised to health promotion attended at least two of the senior meetings, twelve (86%) attended all four senior meetings and the remaining two participants attended three senior meetings.

**Study questionnaire administration**
Following the feasibility goals for data collection, there were missing values from eight participants on in total four out of the nine outcome measures (Table 3). The missing values were predominantly internal missing values, except for values from one participant on life satisfaction. The total time taken to complete the questionnaire at the baseline interview ranged from 68 to 195 minutes (median 108 minutes).

<Insert Table 3 about here>

**Data variability**
As visualised in table 3, the collected data showed good variability, i.e. equal distributions, or small variations across participants, and the scales used. There were outlier values present on both ends of the scales for risk for depression, symptoms, frailty and life satisfaction.

**Discussion**
As a response to the substantial growth of research on health and healthcare inequities, the programme under pilot testing was developed in order to bridge barriers to health promotion and increase the possibilities for persons who are born abroad to live the kind of lives they have reason to value. An evidence-based health promotion programme for ageing persons was adapted, and although much theoretical commonality exists between the original and the adapted protocols, there are some important differences in response to the participants’ socioeconomic contexts.

With migration involving a loss of social networks, persons who are born abroad might become socially vulnerable as they age (51, 52), and in contrast to their native-born counterparts, they are confronted with poorer living conditions and might experience impediments to their possibilities to take control over their health (53). When comparing the study settings of the original and adapted protocols (table 1), it becomes visible how a great amount of people who have migrated to Sweden live in areas with lower socio-economic status, and have lower educational levels. In the light those demographical differences, and previous research (51-53), efforts to improve the opportunities for ageing persons who are born abroad to reach their
desired state of health thus seem to be important from both an ethical and public health perspective. The present findings provide a road map for health promotion, in the visualisation of different barriers to recruitment and implementation, and in the suggestions for how to cross them. There were substantial difficulties with recruiting participants over a reasonable period of time, with both linguistic and structural barriers to cross. Those findings are confirmed by previous research findings, which call for bilingual approaches to both provision and recruitment processes. There seems to be a need to be responsive to each person’s linguistic preferences, and experiences of the use of interpreters (54-56), and the authors of the present study stress the importance of promoting the participants’ freedom of choice in relation to both language and means of communication. A pragmatic approach to identification of potential participants and a combination of different recruitment techniques to be used is suggested in order to increase the possibilities for a larger part of the population to receive information on health promotion and other forthcoming studies. Telephone numbers could perhaps be reached from local healthcare units, and local radio stations and associations could be used for advertising and mediating information. Snowballing or other word of mouth recruitment strategies have also been proven successful for building trust with potential participants (57).

The high retention rates reported in this study indicate that the adaptations were reasonable and that the participants appreciated the senior meetings. Put in relation to previous research on health promotion programmes for persons who have culturally and linguistically diverse backgrounds (32, 34, 35, 38), the person-centred approach might be one explanation for the high retention rates. Although plausible that characteristics associated with migration (reason for migration, linguistic proficiency, integration etcetera.) might be of importance for health promotion with ageing persons who are born abroad, the findings indicate that there are other, equally important, aspects to put focus on. The adapted health promotion programme challenge the current healthcare system’s focus upon functions and achievements (58, 59), and put focus on how each person can convert his or her resources for health into the actual achievement of a desirable state of health. Indeed, healthcare opportunities and professional knowledge ought to be highly valued, but we need to reflect upon how it influences our possibilities to put value in capabilities and human dignity. The findings encourage health professionals to keep philosophical perspectives on what it means to be a person in mind, striving to build authentic relationships between all parties involved in the healthcare encounter. With the aim to facilitate an approach towards each other as persons with capabilities important for health promotion, linguistic and structural barriers could be crossed and the acceptability of healthcare services could be improved in relation to specific target groups. The person-centred approach functioned as a facilitator for acknowledging the different migration experiences and national backgrounds of the participants, and minimised the risk for stigmatisation. Providing an opportunity for participants and providers to discuss the evidence-based programme in relation to the participants’ everyday lives, their resources and
actual needs could be attended to in the very moment of interaction.

The study questionnaire was completed for almost all participants, failing to present complete data from eight out of 40 participants. However, with the missing values being mostly internal, the time to complete the study questionnaire was considered the most serious threat to feasibility. The findings indicate that the administration is too lengthy and difficult to administer with regard to the target group, despite the use of translated questionnaires and bilingual research assistants. One explanation, as described by Bonner and Kanrick (60), might be the difficulties with transcultural interpretations of concepts. The pilot testing of the questionnaire as described in this study is thus important in order to ensure that the participants of the proceeding RCT will understand it. Confirmed by Hussain-Gambles et al. (56), a suggestion is to adapt the study questionnaire in order for it to become more sensitive with regard to the target groups’ linguistic preferences, education and health related beliefs (56). For future RCT development, cautious prioritisation among the outcome measures needs to be made, and a scientifically based system for how evaluators can prioritise among the outcome measures needs to be set up (2). The present findings could be used as guidance, indicating a need for prioritising the outcome measures that have the highest potential for measuring change (i.e. with the greatest level of data variability). The variability of baseline data that is presented is considered to validate the potential for the outcome measures to measure post-treatment change in the proceeding RCT.

**Methodological considerations**

Pilot studies are important to determine the feasibility and sustainability of interventions that are both dynamic and complex (61), and are commonly used to assess methods and procedures in order to detect negative consequences before embarking on a larger study (23). Despite the strength of this pilot study’s systematic approach and evidenced-based foundation, some limitations are worth noting. Firstly, the lack of qualitative data on the acceptability of the health promotion programme requires further exploratory research in order to inform the programme’s readiness for implementation, translation, and sustainability in different community settings (62). Secondly, the high number of primary dropouts indicates an unsure randomisation procedure, that it withstands throughout the larger RCT will impose a risk of selectiveness. However, based on statistical literature on randomisation (63), it is likely that this risk will be minimised as the number of participants increases. Finally, due to the relatively small number of participants, statistical testing of effects was not considered appropriate. It is thus possible that in scaling up the health promotion programme to a full-scale RCT, it will not prove to be beneficial with regard to the target groups. However, considering the premature nature of the research field, it is of relevance to document the early barriers and struggles visualised in this pilot since they will have a large impact of the feasibility of the new procedure of promoting health in the context of ageing and migration.
Key lessons for action

- Apply a pragmatic approach to recruitment with a selection of recruitment techniques to adapt
- Strive for a person-centred approach to programme development, provision and evaluation, with emphasis on purposeful and authentic relationships in order to allow all participants to narrate who they are and what they are capable of doing
- Be responsive to different persons’ preferences with regard to language spoken and use of interpreters
- Develop a sound system for what outcome measures need to be prioritised

Conclusion

In an ageing and increasingly globalised society it is important from both ethical and public health perspectives to explore how healthcare services can become more appropriate for ageing persons who are born abroad. Thus, despite linguistic and structural barriers to recruitment and data collection, the authors of the present study encourage researchers to conduct intervention research with ageing persons who have culturally and linguistically diverse backgrounds. Striving for a collaborative, iterative and pragmatic nature of intervention development, implementation, and evaluation, the findings provide a road map for feasible health promotion that aims to contribute to a more inclusive healthcare environment.

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Contributors

All authors meet the requirements for authorship as defined by the ICJME, and have made substantial contribution to the manuscript. Bilingual research assistants conducted all of the data collection. All analyses were performed by the first author and controlled by the second and third author. All authors provided substantial input to the final interpretation of the analysis, and have provided final approval of the submitted version of the manuscript.

Competing interests

The authors declare no conflict of interest

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**Trial registration**
The study is registered at Clin.Trial.gov (NCT01841853) and has been granted ethical approval by the Regional ethical review board in Gothenburg, Sweden (reference number 001-12).
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