Pilot and Feasibility Studies

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A multidisciplinary, cross-sectorial management program for people living with hand osteoarthritis (HANDY): protocol for a feasibility study

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Abstract

Background People with hand osteoarthritis (HOA) experience difficulties performing activities of daily living (ADL). Referral for occupational therapy is rare despite support for non-pharmacological interventions by international treatment recommendations. HANDY, a multidisciplinary cross-sectorial management program for people with HOA, includes procedures for needs evaluation and referral for occupational therapy performed by general practitioners (GPs) as well as a group-based occupational therapy intervention delivered in municipal rehabilitation settings. The present study aimed to evaluate the feasibility of this first version of the HANDY program (HANDY 1.0).

Methods A feasibility study will be conducted in two municipalities and related general practices to evaluate aspects of the content and delivery of the HANDY program. In accordance with international guidelines for evaluation of feasibility, the aspects evaluated include: intervention development, intervention components, perceived values, benefits, harms or unintended consequences, acceptability in principle, feasibility and acceptability in practice, and fidelity, reach, and dose. Participants will be recruited among people with HOA when visiting their GP, GPs themselves, and occupational therapy clinicians employed in municipal rehabilitation settings. Each municipality will offer the group-based occupational therapy intervention twice, each time involving up to eight participants with HOA. Qualitative and quantitative data will be collected based on registration forms, logbooks, assessments of ADL ability, and qualitative interviews.

Conclusions This study will be the first to examine the feasibility of the content and delivery of the multidisciplinary, cross-sectorial management program HANDY for people living with HOA. It will enable us to determine whether to proceed to a pilot randomized controlled trial evaluating aspects related to trial design, conduct, and processes.

Trial registration Clinicaltrials.gov PRS registry, registration number NCT06254105. Registered 22nd January 2024—retrospectively registered, https://clinicaltrials.gov/study/NCT06254105. Estimated date of study completion was 28th June 2024. However, participant follow-up is still ongoing at the time of submission of the present paper.

Keywords Occupational therapy, General practice, Activities of daily living, Rehabilitation

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Background

Osteoarthritis (OA) occurs with increasing age causing pain and stiffness mostly in knees, hands, and hips. Globally nearly 600 million people are affected, and it is estimated to increase to 642 million in 2050 due to growth and aging populations [1]. Hand OA (HOA) is the second most common OA subtype [1], and clinically HOA presents with three clinical patterns: involvement of the distal and proximal interphalangeal joints, involvement of the thumb base, and a combination of the two [2].

Living with HOA introduces difficulties in performance of Activities of Daily Living (ADL) [3, 4]. ADL involves personal ADL (PADL) tasks carried out every day such as eating, bathing and dressing, and instrumental ADL (IADL) tasks carried out on a weekly basis such as cleaning, cooking, and shopping [3]. People with HOA report spending extra time and/or increased effort and occasionally also need of help to manage ADL [3]. Similarly, observation-based assessments of people with HOA indicate clumsiness and increased effort during ADL task performance [3]. Also, a recent study suggests that ADL ability among people with HOA are lower compared to healthy peers [3].

In 2020, OA was the top-ten leading cause of disability for older adults (> 70 years) [5]. The increasing OA population presenting with decreased ADL ability will lead to a greater burden on the health care system. According to the 2018 European League Against Rheumatism (EULAR) recommendations [6], people with HOA should be offered multidisciplinary and multimodal treatment approaches. Education, training, home modifications, assistive devices, and splints to reduce symptoms and improve overall functioning and quality of life are recommended as non-pharmacological treatment alternatives [6, 7]. Several of these treatment modalities may be employed by occupational therapists (OTs) to improve ADL ability including education, home modifications, assistive devices, and splinting. Still, when exploring current practice of referring people with HOA for occupational therapy among Danish general practitioners (GPs), they are not referred [8]. Moreover, a review of existing literature indicates a lack of standardized, evidence-based occupational therapy interventions addressing decreased ADL ability among people with HOA. Previous intervention studies involving people with HOA have typically focused on improving body functions (e.g., muscle strength) through exercises [9, 10]. Such an approach assumes that improved body functions will lead to increased ability to perform ADL. Research, however, suggests that improved body functions not necessarily translate into improved ADL ability [11, 12]. Rather, existing research support that interventions designed specifically to improve ADL ability also improve ADL ability among people with chronic condition [13–15].

To support the referral of people with HOA to evidence-based occupational therapy addressing decreased ADL ability, a multidisciplinary cross-sectorial management program for people with HOA, named HANDY, was developed. The HANDY program includes (1) procedures for clarifying the need for referral to occupational therapy (needs evaluation) and for referral to occupational therapy, performed by GPs, (2) a group-based occupational therapy intervention delivered in municipal rehabilitation settings, and (3) recommendations for communication and collaboration. Development of the HANDY program was based on the United Kingdom's Medical Research Council's (MRC) framework for developing and evaluating complex interventions [16]. A core element is involvement of stakeholders. Therefore, the research group has worked closely with people with HOA, GPs, OTs, head of rehabilitation services and rheumatologists. Through a co-productional process the first version of the HANDY management program was developed based on research evidence, occupational therapy theory, current best practice, and experiences and preferences among people with HOA. The present study was conducted to evaluate the feasibility of this first version of the HANDY program (HANDY 1.0).

Methods

Aims

The overall aim is to investigate the feasibility of the multidisciplinary, cross-sectorial management program, for people with HOA (HANDY 1.0) in terms of content and delivery of the needs evaluation, referral procedures, the group-based occupational therapy intervention, and the cross-sectorial collaboration.

More specifically, based on the guidance developed by O'Cathain and al. [17] to:

1. Determine to what extent the HANDY program needs to be refined or adapted to make it more acceptable to people with HOA, GPs, and OTs, or more relevant or useful to the specific context in which it is delivered (*Intervention development*),
2. Identify adjustments needed to improve relevance of the HANDY program for people with HOA, GPs and OTs, and determine which aspects are fixed and flexible (*intervention components*),
3. Determine meaningful and beneficial components, and identify unintended positive/negative side effects (*perceived value, benefits, harms, or unintended consequences*),
4. Explore the overall perception of the content and delivery described in the HANDY program and if it

is relevant to implement in practice (*acceptability in principle*),

5. Explore to what extent people with HOA, GPs and OTs do think that the HANDY program can be implemented and if it varies across municipalities/general practices (*feasibility and acceptability in practice),* and
6. Determine the number of referrals in the HANDY program, as well as the number of occupational therapy sessions delivered for people with HOA. Furthermore, the adherence to procedures described for the HANDY program, the duration of each session of the occupational therapy intervention and if the dose was sufficient *(fidelity, reach, and dose)*

In a subsequent pilot randomized controlled trial (RCT), aspects related to trial design will be explored in preparation for a future RCT.

Design, settings

A cohort study design is applied involving people with HOA, GPs, and OTs and employing a mixed-method approach. The feasibility of the HANDY program will be evaluated in two municipalities in the Capital Region of Denmark with approximately 48,000 and 56,000 inhabitants, respectively. In each municipality, general practices and the municipal rehabilitation centre will be involved. The rehabilitation centres are organized under the municipal health administration, whereas the general practices provide treatment for the Danish Health Insurance.

The occupational therapy intervention will be delivered in the homes of people with HOA and in rehabilitation centre settings. In the rehabilitation centres, sessions will be held in contextualized situations, where people with HOA may be engaged in education and practice strategies to improve ADL tasks performance. The HANDY program is expected to be running until each municipality has completed the program, including feedback to the referring GP (medical summary), for two groups of people with HOA.

Participants

The study involves three types of participants: people diagnosed with HOA (four groups with a maximum of eight participants in each), ≥ 18 years, motivated and able to participate in a group-based intervention focusing on improvement in ADL task performance, GPs (three GPs working in general practices in each of the municipalities involved), and OTs (two OTs working in each of the municipal rehabilitation centres involved) with ≥ 6 months of working experience in this type of setting.

Recruitment

OTs and GPs will be recruited during autumn 2023 to allow time for provision of information, instructions and training prior to initiating recruitment of participants with HOA. OTs and GPs will be recruited in the two municipalities and the related general practices, respectively. Invitations to participate include information that participation will run from January to June 2024.

For each GP participation entails; a one-hour on-line introduction to the procedures for needs evaluation and referral for occupational therapy described in the HANDY program manual; identification and referral of approximately five people with HOA to municipal occupational therapy in accordance with the HANDY manual; completion of registration forms addressing conduction of needs evaluations, referrals, and cross-sectorial communication and collaboration, including receiving feedback from the municipality in the form of a medical summary; and subsequent participation in an online individual interview addressing perspectives on the content and delivery of the needs evaluation, referral and the cross-sectorial communication and collaboration.

For each OT participation involves; a 2-day training course in delivering the occupational therapy intervention as described in the HANDY program manual; offering the intervention for two groups of participants with HOA in accordance with the HANDY manual; providing feedback to the GP in a medical summary in accordance with the HANDY manual; completion of registration forms regarding content and delivery of each session of the occupational therapy intervention, and the cross-sectorial communication and collaboration (including feedback to the GP in a medical summary; and subsequent participation in a focus group interview concerning perspectives on the content and delivery of the occupational therapy intervention and cross-sectorial communication and collaboration.

Between January 1st and April 26 th, 2024, potential participants with HOA will be offered needs evaluations in the general practices, and if relevant, referral for occupational therapy. This will be initiated by the GP providing information about the project and obtaining informed consent. Hence, when a person with HOA consults the GP, the GP briefly informs about the research project (e.g., by saying: "this is a project offering a cross-sectorial management program, including a needs evaluation, and if relevant, referral for a group-based occupational therapy intervention addressing problems related to performance of daily activities related to hand OA"), and then asks if he/she is interested in learning more about the project. If the person confirms to be interested, the GP provides additional oral and written information to clarify that participation entails; a needs

evaluation, referral to and participation in a group-based occupational therapy intervention; completion of registration forms; and subsequently, a focus group interview concerning perspectives on the content and delivery of the HANDY program. If the person confirms to participate, the GP obtains written consent as a prerequisite to initiate the HANDY program. When a maximum of eight people with HOA have been referred for occupational therapy in one of the municipalities, they will form a group receiving the occupational therapy intervention.

The cross-sectorial management program (HANDY)

The first version of the HANDY program is developed and manualized to include descriptions of (1) procedures for the GP's evaluation of the person's need for referral to occupational therapy, (2) procedures for referral from the GP to occupational therapy, (3) the group-based occupational therapy intervention, and (4) recommendations related to cross-sectorial collaboration and communication between GP and OT.

Needs evaluation

The purpose of the needs evaluation is to clarify the relevance of referring the person with HOA to occupational therapy. The needs evaluation is conducted, when a person with HOA consults the GP with problems related to HOA, or when problems related to HOA are addressed during a consultation not related to HOA in the first place. The needs evaluation is performed to determine if the HOA affects the person with HOA's performance of ADL tasks. First, the GP asks questions on how the person with HOA perceives using the hands in performance of ADL tasks (e.g., zipping zippers when dressing, cutting nails, opening cans when cooking, or wringing a cloth when cleaning). Then a screening involving seven aspects is conducted: (1) decreased grip strength, (2) problems turning things with the hands, for example turning a key in a lock, or turning a round doorknob or handle, (3) problems related to turning taps on and off, (4) problems peeling vegetables or fruit, (5) problems picking up big, heavy thing, (6) problems wringing a washcloth or dishcloth, and (7), problems related to buttoning buttons. Grip strength is assessed using simple handshake, and the remaining aspects are assessed by asking the person with HOA (i.e., self-report). All aspects are rated as "yes" or "no". The person with HOA is referred to occupational therapy based on rating at least one of the five aspects as "yes".

Referral procedures

Referral is conducted using existing electronic procedures. As part of the referral the GP takes an anamnesis focusing on the level of functioning and the identified problems related to ADL. Also, the specific diagnosis is included. In the municipality, the referral is received and processed according to standard procedures.

Occupational therapy intervention

The occupational therapy intervention follows the Occupational Therapy Intervention Process Model (OTIPM) [18], specifying the steps of a problem-solving process focused on enabling performance of tasks in everyday life. The occupational therapy intervention consists of six mandatory sessions of 120 min representing a combination of individual and group sessions. Each group includes a maximum of eight people with HOA.

Session 1 is an individual session in the person with HOA's home involving evaluations of self-reported and observed ADL ability. Essential elements in session 1 are evaluation of ADL ability and goal setting. The Activities of Daily Living Interview (ADL-I) is used to measure self-reported ADL ability [19, 20], and the Assessment of Motor and Process Skills (AMPS) to measure observed ADL ability [21, 22]. Both ADL-I and AMPS can be used to obtain valid and reliable measures of ADL ability among people with chronic conditions [21, 23]. Following the ADL evaluations, the person with HOA and the OT will collaborate to formulate goals for the intervention using the Goal Attainment Scale (GAS) and together consider reasons for decreased ADL ability [24].

Sessions 2 to 5 are group-based, held at the rehabilitation centre, and involve peer learning activities. The essential element in session 2 involves introduction of the people with HOA on how they can identify factors influencing their individual ADL task performances (using the Transactional Model of Occupation (TMO)) in plenum [18]. The results of this individual analysis form the basis for sessions 3 to 5 focusing on improving ADL ability by addressing these factors. The essential elements are mainly based on compensatory strategies to improve ADL task performance by energy conservation (session 3), and assistive devices and the use of orthoses (session 4). The last group session also addresses how a broader spectrum of tasks (e.g., ADL, leisure, or social activities) may be used to maintain hand function (session 5). The group sessions are individualized based on the people with HOA's individual problems performing ADL tasks. The occupational therapy intervention is completed with an individual session (session 6) in the person with HOA's home. Here the essential elements involve evaluation of goal attainment and changes in self-reported and observed ADL ability using GAS, ADL-I, and AMPS [21, 23, 24].

Cross-sectorial communication and collaboration

Immediately after the final session of the occupational therapy intervention, the OT submits a medical discharge summary to the GP, including information on the level of goal-attainment, obtained changes in ADL-I and AMPS measures, descriptions of any referrals to other services (e.g., physiotherapy or assistance in the home) and future recommendations.

Training of GPs and OTs

To support delivery of the HANDY program according to the manual (fidelity), the participating GPs and OTs will be trained in procedures related to content and delivery. GPs will in a 1-h online session be trained in the procedures of needs evaluation, referral, and cross-sectorial collaboration. The OTs will participate in a 2-day workshop including introduction to underlying theories (OTIPM, TMO [18]) and practicing delivery of the occupational therapy intervention, including evaluations of self-reported and observed ADL ability, procedures for goal setting using GAS, and the cross-sectorial collaboration procedures.

Data collection

Data gathered will comprise participant demographic data, and data on feasibility outcomes. A combination of registration forms, pre/post measures of ADL ability and goal attainment, interviews, and logbooks will be employed (Fig. 1 and Table 1).

Demographic data on participants with HOA will including age, sex (male/female), co-morbidity, social status (living alone/living with spouse/living with children/others), level of education (primary and lower secondary/vocational/upper secondary/short-cycle/medium-cycle/long-cycle), and employment (working/unemployed/on sick leave/retired/studying/other); while demographic data on GPs and OTs will include information on age, sex, and years working as health professionals.

Data on feasibility outcomes will be collected based on a mixed-methods approach to explore aspects of content and delivery (i.e., acceptability, relevance, utility, adjustments made, meaningful and beneficial intervention components, unintended side effects, implementability, recruitment, dose, and adherence) as illustrated in Fig. 1 and Table 1 [17]. Quantitative data include session specific registrations forms collected among participants with HOA receiving, and GPs and OTs delivering, the HANDY program, and measures of ADL ability and goal-attainment collected among participants with HOA. Qualitative data encompass interviews conducted among participants with HOA receiving, and GPs and OTs delivering the HANDY program; and logbooks managed by researchers. Data will be collected according to the timeline in Fig. 1.

Registration forms

Registration forms are developed to inform all specific objectives: (1) intervention development, (2) intervention components, (3) perceived value, benefits, harms or unintended consequences, (4) acceptability in principle, (5) feasibility and acceptability in practice, and (6) fidelity, reach and dose (Table 1). Responses across registration forms include "yes/no" and five-point ordinal scales (from 1 = to a very low degree to 5 = to a very high degree), in both cases with the possibility of adding comments.

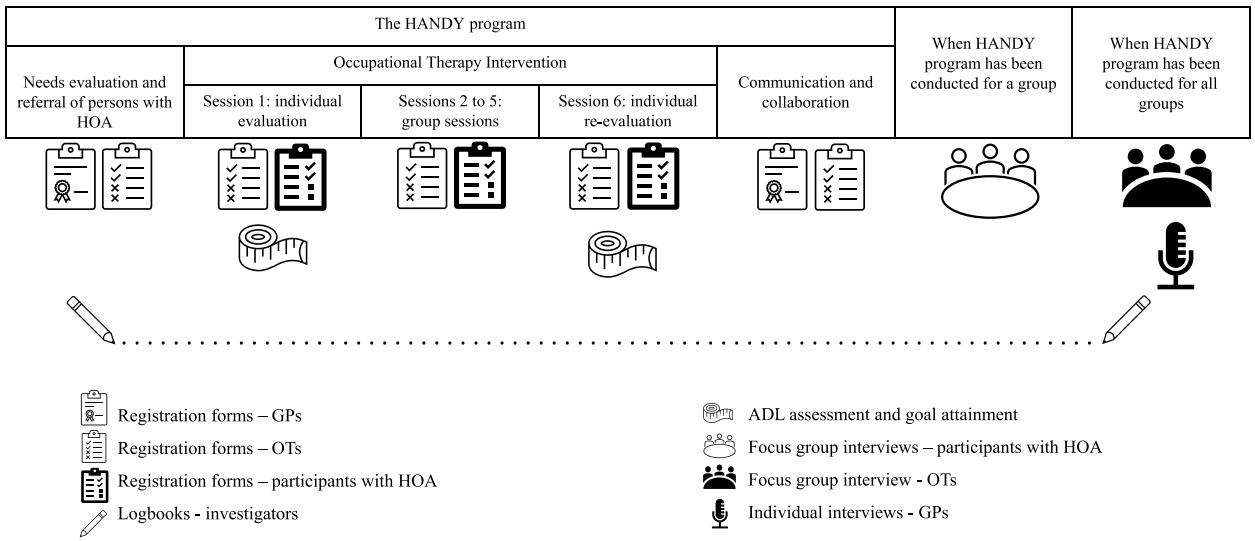

Fig. 1 The data collection process

Table 1 Specific objectives and related data collection methods

	Intervention development	Intervention components	Perceived value, benefits, harms, or unintended consequences	Acceptability in principle	Feasibility and acceptability in practice	Fidelity, reach, and dose
Specific objectives	1. To what extent does the HANDY program needs to be refined or adapted to make it more acceptable to people with HOA, GPs and OTs, or more relevant or useful to the specific context in which it is delivered	2. Which adjustments must be made to improve relevance of the management program for people with HOA and clinicians. Which aspects are fixed and flexible	3. Determine meaningful and beneficial components, and identify unintended positive/negative side effects	4. Explore the overall perception of the content and delivery described in the HANDY program and if it is relevant to implement in practice	5. Explore to what extent people with HOA, GPs and OTs do think that the HANDY program can be implemented and if it varies across municipalities/general practices	6. Determine number of referrals in the HANDY program, and number of occupational therapy sessions delivered for each participant with HOA Adherence to procedures described in the HANDY program, duration of each session of the occupational therapy intervention and if the dose was sufficient
Data collection methods	Session specific registration forms filled in by GPs, OTs, and participants with HOA Logbooks managed by investigators Interviews with GPs, OTs, and participants with HOA Assessment of ADL ability (ADL-I, AMPS), GAS					Numbers of completed ADL-I, AMPS, and GAS
Feasibility outcomes	Acceptability, relevance, utility	Adjustments made and reason for this	Meaningful and beneficial components, unintended side effects Change in ADL ability and level of goal attainment	Relevance and implementability	Implementability	Recruitment, dose (number of sessions and minutes per session) and adherence

GPs will fill in registration forms at two time points (Fig. 1). First time immediately after conducting a needs evaluation, and potential referral, to inform on content and delivery of these (i.e., results of the needs evaluation, duration in minutes, adherence to manual, unintended side effects, and practical and/or organizational facilitators and barriers, perception of needs evaluation and referral procedures). For example, the GPs will be asked to rate "if the screening questions were relevant" on the five-point ordinal scale. Second time after receiving feedback from the municipality in the form of a medical summary from the OT to inform on relevance and implementability of the cross-sectorial collaboration (i.e., perception of communication and collaboration with OT). Moreover, to inform reach, the GPs will document how they identified potential participants with HOA relevant to the project (i.e., if the consultation was related to HOA, if the consultation was related to something else but the client mentioned problems related to HOA, or if the consultation was related to something else, but the GP brought it up). Finally, the GPs will document the number and sex of persons with HOA declining the invitation to participate based on the initial information to inform recruitment.

OTs will complete registration forms at multiple time points (Fig. 1). Registration forms will be completed after each of the six occupational therapy intervention sessions to inform the content and delivery of the sessions (i.e., individual assessments, goal setting and group sessions with presentations, participants' engagement, practical exercises, duration in minutes, unintended side effects, practical and/or organizational facilitator and barriers, perception of the essential elements in the six sessions). For example, the OTs will be asked to rate the degree to which 'he/she was satisfied with the delivery of this session'. Furthermore, the OTs will complete a registration form after submitting a medical summary to the GP, to report on relevance and implementability of the cross-sectorial collaboration (i.e., perception of communication and collaboration with GP). To inform reach and dose, the OT will document each referral received from the GP, as well as which sessions the individual participant with HOA has received. To inform on adherence both OTs and GPs will be asked to record, if they have delivered session specific intervention components according to the manual, including reasons for deviations, and potential side effects.

Finally, participants with HOA will complete registration forms to inform the content and delivery of the needs assessment, referral and each of the six occupational therapy sessions. For example, participants with HOA will be asked to rate the degree to which "the period between the needs assessment and the first contact to the occupational therapists was acceptable". After the first occupational therapy session, participants will rate the feasibility of the needs assessment, referral, individual assessments and goal setting. Subsequently, following each of the remaining sessions, the participants with HOA will rate the feasibility of the content and delivery of each session (i.e., presentations, exchange of experiences between peers, practical exercises as well as the safety in the group, re-evaluations and achievement of goals). To ensure confidentiality participants with HOA will hand in their registration forms to the OT in closed envelopes at the end of each session.

All registration forms will be filled in independently.

Logbooks

Investigators will be managing logbooks continuously, addressing any of the research objectives. Based on recommendations from Moore et al. [25], stating that to record and understand occurring problems related to implementation of a new intervention, investigators need to be "*close enough to the intervention to record these problems and understand why they occurred, yet sufficiently independent to report them to intervention stakeholders honestly*" (p. 3), collaborative relationships between clinicians and investigators will be established. Due to the overall aim of this study to revise the HANDY program rather than evaluate it, the investigators will play a relatively active role during the study period. Hence, ongoing collaboration between participating clinicians and researchers will be allowed to discuss emerging challenges and continuously implement relevant and needed adaptations in the specific contexts. Information regarding all contacts and adaptations applied will be registered in diary notes by the researchers.

ADL assessments and goal attainment

To address *Perceived value, benefits, harms, or unintended consequences* (objective 3) changes in ADL ability among participants with HOA will be determined using information on self-reported (ADL-I) and observed (AMPS) ADL ability, gathered as part of the occupational therapy intervention, in sessions 1 and 6 [19, 20]. The ADL-I and the AMPS have demonstrated sensitivity to change among persons living with chronic conditions [19–22]. Similarly, the level of goal attainment will be determined based on the GAS, employed [24].

The ADL-I is a standardized measure of self-reported quality of ADL task performance based on interview involving effort, efficiency, safety and independence when performing 47 ADL tasks [19, 23]. Raw ordinal scores are converted to interval scale measures of ADL ability adjusted for task difficulty and reported in logits. ADL-I

measures range from −5.81 to 6.38 logits [19], where higher positive measures represent more ADL ability.

The AMPS is a standardized measure of observed quality of ADL task performance assessment in terms of effort, efficiency, safety, and independence. The calibrated AMPS rater (OT) observes the person while performing two relevant and challenging standardized ADL tasks [21, 22]. AMPS includes 16 ADL motor items and 20 ADL process items to be rated on a four-point ordinal rating scale for each task performed [21]. The raw ordinal scores are converted to interval scale measures of ADL ability adjusted for task difficulty and rater severity. Higher positive measures indicate more ADL ability. Competent ADL task performance is associated with > 2.0 logit on AMPS ADL motor and > 1.0 logit on AMPS ADL process.

Interviews

Qualitative semi-structured interviews addressing objectives (1) intervention development, (2) intervention components, (3) perceived value, benefits, harms or unintended consequences, (4) acceptability in principle, and (5) feasibility and acceptability in practice will be conducted among all participants to elaborate on information provided in the completed registration forms. Interviews with participants with HOA will be conducted in face-to-face focus groups corresponding with the occupational therapy intervention groups, immediately after completing the last session of the occupational therapy program. OTs will be interviewed in one face-to-face focus group including all OTs across groups and municipalities, and GPs will be interviewed individually online. All interviews with clinicians will be conducted immediately after completion of the HANDY program i.e., when the OTs have forwarded medical summaries on all participants with HOA to the referring GPs. This is expected to be completed by July 5th 2024.

Interview guides will be developed based on the same topics as addressed in the registration forms. Hence, interviews with participants with HOA will include questions related to content and delivery of individual and group sessions in the occupational therapy program, needs evaluation and referral procedures; while interviews with OTs will focus on the overall occupational therapy intervention and the cross-sectorial communication and collaboration; and finally, interviews with GPs will focus on the needs evaluation, referral procedures, and the cross-sectorial communication and collaboration.

Considering that topics reflecting low and/or various scores in the registration forms are of certain interest, when revising the HANDY program, the filled-out registration forms will be studied while developing the interview guides. Hence, questions related to topics of such interest will be incorporated in the interview guides to provide detailed information on important topics. Moreover, the interview guides will include questions concerning how the participants experienced the content and delivery in both principle and reality, to address acceptability in principle and practice, respectively.

Focus group interviews will be conducted by two researchers. The primary interviewer will be a researcher having extensive knowledge of the HANDY program, while the secondary interviewer will have experience from development and evaluation of other group-based occupational therapy interventions. Both researchers will be trained interviewers.

Individual interviews with GPs will be conducted by two investigators having extensive knowledge of the HANDY program and being experienced interviewers.

Sample size

Since the overall aim of the study is to assess if the content of this first version of the HANDY program can be delivered as intended, the clinicians need to get experience in delivering the program. Accordingly, the study is expected to be running until each municipality has completed the program for two groups of up to eight people with HOA. Consequently, the sample size is estimated to a maximum of 32 participants with HOA receiving the HANDY program, and six GPs and four OTs delivering the program. This sample size is in line with the median number of participants in feasibility studies identified in an audit by Billingham et al. [27], and considered representative and large enough to provide information related to the feasibility of the HANDY program [27, 28].

Data analysis

Nominal data will be reported based on numbers and percentages. Continuous variables will be reported in means and standard deviations (SDs), provided data are normally distributed. Ordinal data and continuous data with lack of normal distribution will be presented based on medians and ranges.

Demographic data

Demographic data on participants with HOA (i.e., age, sex, social status, level of education, employment, and ADL ability) and clinicians (i.e., age, sex, and years working as GP or OT) will be presented.

Registration forms

The number of participants with HOA recruited and the retention rate will be presented in a flow chart. Reach will be analyzed by investigating the flow chart to characterize the persons who the intervention reached. Persons

with HOA referred for occupational therapy, but never completing session 1 will be considered as drop-outs.

Data concerning what and how much was delivered (i.e., frequency and median number of minutes used for needs evaluation, referrals, and implemented occupational therapy intervention sessions) will be presented.

Likert scores on aspects related to perception of needs evaluation, referral procedures, occupational therapy program sessions, and cross-sectorial collaboration will be presented using medians with ranges. This will include, e.g., perception of involvement, meaningfulness, and satisfaction from the perspectives of participants with HOA; perception of relevance of questions in needs evaluation, and effectiveness of cross-sectorial collaboration from the perspective of GPs; and perception of content of the occupational therapy intervention, collaboration with the person with HOA, engagement, and meaningfulness from the perception of OTs.

Data concerning deviations from the manual, unintended side effects, practical and/or organizational facilitators and barriers from the perspectives of the OTs and GPs, will be summarized and supported by quotes presented in text.

Evaluation of ADL ability and goal attainment

The proportions of participants with HOA with a clinically relevant improvement in self-reported (ADL-I) and observed (AMPS) ADL ability will be presented. A clinically relevant change on the ADL-I is ≥ 0.64 logits [19, 20] Similarly, a clinically relevant change on the AMPS is ≥ 0.3 logits [21, 22].

The proportion of participants with HOA achieving goals, as well as number and percentage of goals achieved will be reported. The levels of goal attainment on the GAS range from -2 to $+2$(25). Level -1 ("less than expected") represents the participant's current (or baseline). Level 0 ("expected level") represents a level to be reached within a defined time span. Levels $+1$ and $+2$ represents levels "better or much better than expected". In contrast, the level -2 ("much less than expected" represents an aggravation. Accordingly, goals reaching the level of zero or higher at session 6 in the occupational therapy intervention, will be considered goals achieved.

Logbooks and interviews

Qualitative data, including interview data and logbook notes, will be analyzed and interpreted in six steps using principles of qualitative content analysis (Table 2) [26]: I1) interview data will be transcribed verbatim; (2) transcriptions and logbooks will be read through to obtain a sense of the whole; (3) units of analysis, i.e., content and delivery of the elements of the HANDY program in terms of "cross-sectorial collaboration" (needs evaluation, referral procedure, and communication and collaboration) and "the occupational therapy intervention" (individual evaluation, group-based sessions, and individual re-evaluation) will be identified in transcriptions and logbooks; (4) Within each unit of analysis, meaning units, i.e., content related to objectives 1 to 6, will be identified and coded accordingly; (5) meaning units will be condensed, i.e., shortened while still preserving the core; (6) through interpretation of content in meaning units underlying meaning will be described. The process in this step will emphasize descriptions and interpretations on a higher logical level.

A subgroup of authors will be involved in the qualitative content analyses. Step 2 will be conducted individually by at least three authors. Steps 3 to 5 will be conducted by one author in relation to "cross-sectorial collaboration", and another author in relation to "the

Table 2 Analysis of qualitative data

Step	Task	Details					
Step 1	Transcriptions	All interview data					
Step 2	Reading	To obtain sense of the whole. Involves all transcriptions and logbooks					
Step 3	Units of analysis	Content and delivery of the HANDY program					
		Cross-sectorial collaboration			The occupational therapy intervention		
		Needs evaluation	Referral procedure	Communication and collaboration	Session 1: individual evaluation	Sessions 2 to 5: group sessions	Session 6: individual re-evaluation
Step 4	Meaning units (coding)	Content areas related to objectives 1 to 6: intervention development; intervention components; perceived values, benefits, harms, or untended consequences; acceptability in principle; feasibility and acceptability in practice; and fidelity, reach, and dose. Meaning units can represent more than one objective					
Step 5	Condensation of meaning units	Shortening while still preserving the core					
Step 6	Interpretation of underlying meaning	Like step 5. Emphasizes descriptions and interpretations on a higher logical level					

occupational therapy intervention", together with one author involved in both parts. Finally, step 6 will be conducted by all authors involved in a collaborative process until consensus is reached.

The results of qualitative analysis will be presented in text within each objective, using quotes to document the findings.

Ethics

The study will be conducted in accordance with the Helsinki declaration and Danish law. The local research ethics committee decided that according to Danish law, the study does not need approval. The participants are insured by the Danish Patient Compensation [29].

Informed consent will be obtained from each participant, including participants with HOA, GPs, and OTs, emphasising the rights to withdraw from the study at any time. It is the responsibility of the recruiting personnel to ensure that any potential participant has gained an understanding of the information given. A copy of the consent form will be provided to participants and the first author will be responsible for saving a consent form in the participant's study file. Each participant is provided an ID number, with which all data is pseudonymized and only accessed by authorized personnel obliged to secrecy. Study participation is not expected to be associated with risks or complications. To minimize any risk all participating GPs and OTs will receive training in the procedures of the HANDY program to ensure delivery by skilled personal.

The results of the study will be reported in accessible formats to study participants, decision makers in the participating municipalities, other stakeholders involved in the study, and public in general. Further, results will be published in peer-reviewed journals and presented on national and international conferences.

Discussion

This study will determine the feasibility of a new multidisciplinary, cross-sectorial management program (HANDY) for people with HOA (v. 1.0) in terms of content and delivery of needs evaluation, referral procedures, an occupational therapy intervention, and cross-sectorial collaboration. The study is innovative in several ways. First, based on a recent audit in Danish general practices(8), the HANDY program was developed to accommodate the need for referral of persons with HOA in need of occupational therapy. In the long term, the HANDY program may ensure identification and referral of people with HOA in need of occupational therapy to a brief, effective and cost-effective, group-based municipal occupational therapy program in agreement with international treatment recommendations supporting non-pharmacological interventions as first line treatment [6].

The HANDY program was designed in accordance with the United Kingdom MRC framework for development of complex interventions [16]. Since involvement of a combination of the target group and intervention deliverers through co-production has been shown to improve adaptation and tailoring of intervention content to a specific context [30, 31], the first version of the HANDY program was co-produced with relevant stakeholders including people with HOA, GPs, OTs, head of rehabilitation services and rheumatologists. The co-production process involved combining research evidence, occupational therapy theory, current best practice, and experiences and preferences among people with HOA and clinicians.

This study has been designed to test the feasibility of delivering the content of the HANDY program in two Danish municipalities involving municipal rehabilitation settings and general practices located in the municipalities. Inclusion of two municipalities and several general practices in the study will help increase the study results external validity [32]. The program will be delivered by clinicians employed in the settings involved but with no established routines related to conducting needs evaluations, referring or offering occupational therapy for people with HOA. By involving clinicians in testing the content and delivery, the study results will provide information to understand how and where the elements of the HANDY management program can be implemented into routine clinical practice and by whom. The combined qualitative and quantitative data will therefore support further development and refinement of the HANDY program, including a program theory. In several workshops, results will be shared and discussed with the stakeholder group, i.e., people with HOA, GPs, OTs, head of rehabilitation services and rheumatologists, to inform and qualify decisions related to revisions of the content and delivery of the program prior to initiating a pilot RCT study.

The feasibility study will also be associated with some limitations. The study will not enable evaluation of overall effectiveness of the HANDY program, nor will it evaluate the effectiveness of the occupational therapy intervention, specifically. However, a feasibility study of the content and delivery of a new intervention is common as a first step in the development process in preparation for future evaluation studies [33, 34]. If the HANDY program proves feasible in terms of content and delivery, a pilot randomized controlled trial (RCT) addressing aspects related to trial design, conduct and processes will be conducted in preparation for a future RCT.

Trial status

Recruitment of participants with HOA ended May 8th, 2024. Follow-up is still ongoing at the time of submission of the present paper.

Abbreviations

ADL	Activities of daily living
ADL-I	Activities of Daily Living Interview
AMPS	Assessment of Motor and Process Skills
EULAR	European League Against Rheumatism
GAS	Goal Attainment Scale
GP	General practitioner
HOA	Hand osteoarthritis
MRC	United Kingdom's Medical Research Council
OA	Osteoarthritis
OT	Occupational therapist
OTIPM	Occupational Therapy Intervention Process Model
RCT	Randomized controlled trial
SD	Standard deviation
TMO	Transactional Model of Occupation

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Authors' contributions

EEW, UA, and VH conceived the original idea and outline of the study, and CvB, AD, HG, and HB contributed to designing the study. UA, VH, and EEW wrote the study protocol. All authors discussed and commented on draft versions and approved the final version.

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Data availability

Data will be available on request given the specified purpose.

Declarations

Ethics approval and consent to participate

The Danish Data Protection Service Agency approved the trial (Journal-nr. p-2023–15247) and the Ethical Committee in the Capital Region of Denmark deemed the study protocol exempt from approval (Journal-nr. F-23073797).

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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