

Occupational therapy as part of a cross-sectorial management programme for individuals with hand osteoarthritis (HANDY): pilot and feasibility randomised controlled trial

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Abstract

Background:

Individuals with hand osteoarthritis (HOA) often experience decreased ability to perform Activities of Daily Living (ADL) tasks. This pilot study aimed to evaluate the trial design and remaining feasibility aspects of an occupational therapy intervention (HANDY-OT v2.0) designed to improve quality of ADL task performance.

Methods:

The study was a pilot randomised controlled trial. Participants were randomised 1:1 to HANDY-OT or awaiting-list control in two Danish municipalities. Eligible participants were ≥ 18 years, diagnosed with HOA and experienced decreased ADL ability. Pilot trial evaluation of recruitment, retention, acceptability of procedures, appropriateness and completeness of outcomes was guided by predefined 80% progression criteria. Outcome assessments were carried out at baseline and post intervention. Evaluation of feasibility and acceptability of HANDY-OT was assessed through sessions attendance records and registration forms completed following each HANDY-OT session by both participants and occupational therapists. Descriptive statistics were used to analyse all data.

Results:

The study included 32 participants with HOA (16 in the intervention group and 16 in the waiting list control group) and four occupational therapists. The progression criteria were fulfilled for acceptability of randomisation ($n = 32$ [100%]) and retention ($n = 29$ [91%]). All 29 participants completed the post-intervention tests with no missing data. Recruitment was amended due to initial low referral rates. Adherence in the intervention group was $n = 13$ (81%). Registration forms showed a median high or very high agreement with the feasibility aspects across sessions.

Conclusion:

Overall, the findings support progression to a full-scale RCT of the HANDY-OT v2.0 with minor methodological refinements.

Background

Individuals with hand osteoarthritis (HOA) often experience decreased ability to perform Activities of Daily Living (ADL), affecting both personal and instrumental ADL tasks. This compromises their independence and participation in everyday life (1–4). Despite evidence that occupational therapy interventions are effective in improving ADL ability among individuals with chronic conditions (5–7), structured occupational therapy services that target ADL limitations for individuals with HOA remain underutilised in clinical practice. Still, only a limited number of rigorous studies have evaluated occupational therapy interventions involving compensatory strategies (e.g., strategy training, assistive devices and splints) to improve ADL ability in individuals with HOA (8, 9). A recent audit demonstrated that there is a substantial mismatch in Danish general practices between reported ADL limitations among individuals with HOA and referral to occupational therapy, which highlights a critical gap between need and service provision (10).

To address this gap, a multidisciplinary, cross-sectorial management programme (HANDY) for individuals with HOA was developed using the United Kingdom's Medical Research Council's (MRC) framework for developing and evaluating complex interventions (11). The HANDY management programme consists of an organisational component designed to strengthen needs evaluation, referral pathways and collaboration across sectors, and an occupational therapy intervention (HANDY-OT) designed to improve individuals' ADL ability through compensatory strategies (12). The development of the HANDY management programme followed an iterative process which involved stakeholders, including clinicians (i.e., general practitioners (GPs), occupational therapists, rheumatologists) and individuals with HOA, to enhance its relevance, acceptability and sustainability (13). Through this process, the content and the delivery of the programme were aligned with the experiences and preferences of individuals with HOA and clinicians, as well as with existing evidence (5, 14–19).

A prior study addressing the feasibility of the initial version of the HANDY management programme in terms of content and delivery had identified several areas that required refinement, including the needs evaluation procedures, referral processes, session structure and homework tasks (12, 20, 21). These findings informed the development of a revised version of the HANDY management programme, including the occupational therapy intervention HANDY-OT (v2.0). At this stage of intervention development (11), the remaining uncertainties primarily concern whether the HANDY-OT v2.0 is feasible and acceptable in practice, and whether the study procedures, such

as recruitment, randomisation and outcome assessments, are acceptable and workable, and whether the selected outcome measures are appropriate for a full-scale randomised controlled trial (RCT). In this context, outcome measures are used to inform decisions, including whether selected outcomes appear suitable for capturing variation relevant to the design of a future full-scale RCT.

Consistent with the MRC framework for complex interventions (11) and the guidance for feasibility research by O’Cathain et al. (22), the overall aim of this pilot and feasibility RCT was to evaluate the remaining feasibility aspects of the HANDY-OT v2.0 and to pilot key elements of the trial design.

Specifically, the objectives were:

1. to pilot central aspects of the trial design, conduct and processes in terms of:

- effectiveness of recruitment, randomisation, and retention to trial procedures (i.e., completion of baseline and post-intervention assessments) (*Recruitment and retention*).
- acceptability of study procedures (*Acceptability of the trial in practice*).
- appropriateness of outcomes and measurements, including whether selected outcomes appear responsive and capable of capturing meaningful variation or change relevant for a future full-scale RCT (*Breadth and selection of outcomes*).
- completion of outcome measures (*Completion of measures*).

1. to evaluate remaining feasibility aspects to:

- explore if participants with HOA and occupational therapists experienced HANDY-OT v2.0 as feasible and acceptable (*Feasibility and acceptability in practice*).
- evaluate intervention adherence in terms of number of HANDY-OT sessions attended by the participants in the intervention group (*Feasibility and acceptability in practice*).

Methods

Study design and settings

The study was designed as a two-armed parallel pilot RCT (Fig. 1) with a waiting-list control group, conducted in accordance with the CONSORT guideline for pilot and feasibility trials (23). Following baseline trial assessments, the participants were randomised to either HANDY-OT or a waiting-list control group which reflected usual care (i.e. no occupational therapy intervention during the study period) (Fig. 1). Trial outcome assessments were conducted at baseline and post-intervention (week 7). After study completion, participants allocated to the waiting-list group were offered HANDY-OT.

The study was conducted between January 1st and June 30th, 2025, in two municipal rehabilitation centres located in the Capital Region of Denmark. Both centres had previously participated in the first feasibility study of the HANDY management programme (v1.0) (12).

HOA, hand osteoarthritis. OTs, occupational therapists. RCT, randomised controlled trial.

Participants and recruitment

Adults (> 18 years) diagnosed with HOA by their GP were eligible if they reported decreased ADL ability due to HOA and had no severe sensory or cognitive impairment that would affect their participation in group-based intervention. Individuals were excluded if they were unable to attend two or more group sessions or if their ADL problems were primarily attributable to acute illness.

Participants with HOA were recruited through two complementary approaches. First, GPs affiliated with the municipalities delivering HANDY-OT were introduced to a structured quick guide describing the needs evaluation and referral procedures of the HANDY management programme. They were instructed to follow these procedures when assessing whether HOA affected the individual’s ADL ability and whether referral to occupational therapy was indicated. Second, posters displayed in GP clinics and municipal rehabilitation centres provided information about the study, eligibility criteria and contact information, encouraging individuals with HOA to request referral from their GP. Following referral, the first author and a research assistant screened individuals for eligibility. Eligible individuals received oral and written information about the study and provided written informed consent prior to inclusion. The first author monitored participant flow throughout the trial flow using registration forms documenting recruitment, randomisation, assessment and withdrawals.

Occupational therapists delivering HANDY-OT were selected by the municipal management, based on a minimum of six months' experience in municipal rehabilitation and an interest in group-based intervention targeting ADL task performance for individuals with HOA. Prior to study initiation, the occupational therapists received training in HANDY-OT procedures and were encouraged to seek clarification from the research team, if uncertainties arose during intervention delivery.

The HANDY management programme

Organisational component

The organisational component of the HANDY management programme comprises a structured needs evaluation, referral procedures and cross-sectorial communication. Needs evaluation and referral are conducted by the GP in accordance with the procedures outlined in the quick guide of the management programme (21). The needs evaluation consists of a six-item screening tool (Fig. 2) developed and refined based on findings from the previous feasibility study (21). Each item is rated yes/no, and referral to occupational therapy is initiated if more than one item is rated yes.

As part of the referral, the GP provides a brief medical history focusing on the level of functioning, identified ADL task performance problems, and diagnosis. Referrals are received and processed by municipal rehabilitation services according to the HANDY management programme guidelines.

HOA, hand osteoarthritis. OTs, occupational therapists.

Following completion of HANDY-OT, the occupational therapists submit a structured discharge summary to the GP, including information on goal attainment, changes in self-reported and observed ADL ability, referrals to other services (e.g., assistive devices or assistance in the home) and recommendations for future management.

Occupational Therapy Intervention

HANDY-OT v2.0 is designed to address ADL task performance problems through compensatory strategies and is guided by the Occupational Therapy Intervention Process Model (OTIPM) (24), which represents a systematic, client-centred and evidence-based approach to occupational therapy practice. The intervention comprises six mandatory sessions of 120 minutes each and combining individual and group-based sessions. Group sessions include a maximum of eight participants with HOA and are facilitated by two occupational therapists.

Session 1 and session 6 are conducted as individual home-based sessions and form part of intervention delivery. During these sessions, the occupational therapists conduct intervention-related evaluations of participant's self-reported and observed ADL ability using the Activities of Daily Living Interview (ADL-I) (25) and the Assessment of Motor and Process Skills (AMPS) (26, 27), respectively. The findings from these evaluations form the basis for a collaborative goal setting between the individual with HOA and the occupational therapist using the Goal Attainment Scale (GAS) (28) and guide subsequent intervention planning. The repeated use of ADL-I and AMPS in the intervention supports the evaluation of changes in ADL task performance over the course of HANDY-OT. These intervention-related evaluations should be distinguished from trial outcome assessments, which were conducted for research purposes at baseline and post-intervention.

Sessions 2–5 are group-based and delivered at the municipal rehabilitation centre. Group sessions consist of a combination of presentations led by the occupational therapist, peer dialogue and practical peer-learning activities tailored to participants' ADL task performance problems, identified during session 1. The overall focus is on adapting task and environmental factors to enhance the quality of participants' ADL task performance. In Session 2, participants are introduced to the Person–Environment–Occupation (PEO) model (24) to support their understanding of how ADL task performance problems arise through interactions between personal, environmental and task related factors (21). Factors identified through the PEO model in session 2 formed the foundation for sessions 3 to 5, still focused on improving participants' ADL task performance by addressing these factors.

Across sessions, the intervention emphasises compensatory strategies to improve ADL task performance (14, 17, 18, 29), including energy conservation strategies (session 3), use of assistive devices and orthoses (session 4), and strategies for maintaining hand function through engagement in a broader range of tasks, such as ADL, leisure and social activities (session 5).

Study procedures

Sample size

The HANDY-OT was delivered once in each municipality with groups of up to eight participants, resulting in a total planned sample of 32 individuals with HOA (16 per centre). This sample size was considered sufficient for a pilot and feasibility RCT to evaluate recruitment, retention, acceptability, data collection procedures and outcome behaviour, and to inform decisions regarding progression to a future full-scale RCT, in line with methodological recommendations for feasibility studies (30, 31).

Randomisation

Following completion of baseline trial assessments, participants were randomised to either HANDY-OT or a waiting list control group using a computer-generated allocation sequence implemented in Research Electronic Data Capture v14.1.2 (REDCap) (32). Allocation concealment was ensured, and the researcher, responsible for enrolment remained blinded to the randomisation list throughout the allocation process. Reasons for withdrawal after randomisation were documented.

Data collection

Data collection methods were aligned with the predefined study objectives (Table 1) and followed recommendations for feasibility studies. (22). Demographic data were collected at baseline. Trial outcome assessments were conducted at baseline and post-intervention (week 7) in participants' home by the first author and two trained research assistants (Fig. 1).

Predefined progression criteria were applied to trial design aspects (recruitment, retention, acceptability of trial procedures, and completion of measures) to guide interpretation of findings and decisions regarding progression to a future full-scale RCT (33) (Table 1). Remaining feasibility aspects, including intervention adherence and acceptability in practice, were explored descriptively without formal progression criteria and interpreted in relation to findings from the prior HANDY v1.0 feasibility study (12, 20, 21).

Table 1
Study objectives and related data collection methods.

Trial design, conduct and processes					Remaining feasibility aspects	
	Recruitment and retention	Acceptability of trial in practice	Breadth and selection of outcomes	Completion of measures	Feasibility and acceptability of intervention in practice	
Specific objectives	Pilot central aspects of trial design in terms of effectiveness of recruitment, randomisation and retention to trial procedures (completion of baseline and post-intervention assessments).	Pilot central aspects of trial design in terms of acceptability of study procedures.	Pilot central aspects of trial design in terms of appropriateness of outcomes and measurements.	Pilot central aspects of trial design in terms of completion of outcome measurements.	Evaluate feasibility aspects to explore if HANDY-OT is feasible and acceptable, based on adjustments made.	Evaluate intervention adherence in terms of number of HANDY-OT sessions attended by participants in the intervention group.
Data collection methods	Registration of participants participating in baseline/ post intervention tests, randomisation.	Registration forms completed by participants with HOA following baseline test and randomisation.	Diary entries completed by participants with HOA.	Completion rates of outcome measurements at baseline and post intervention.	Registration forms filled in by occupational therapists and participants with HOA after each session.	Registration forms completed by occupational therapists and participants after each session.
Data analysis	Number and percentage of participants referred, included, randomised, and completing baseline and post-intervention assessments.	Questions addressing trial procedures presented with medians and IQR.	Number and extent of completion of diary entries.	Number of participants completing baseline and post intervention tests.	Registration forms presented as medians with ranges.	Number of participants completing all mandatory sessions (session 1 & 6 + ≥ 3 of 4 group sessions).
Progression criteria	Can 16 individuals per municipality be recruited?	Can 80% of participants participate in randomisation and complete baseline and post-intervention assessments?	Can 80% of the participants with HOA accept the duration of baseline test and randomisation?	n.a.	Can 80% of the participants complete baseline and post intervention assessments?	n.a.
	Go: n = 16	Go: $\geq 80\%$	Go: $\geq 80\%$		Go: $\geq 80\%$ accept	
	Amend: n = 10–15	Amend: 79 – 50%	Amend: 79 – 50%		Amend: 79 – 50%	
	Stop: n = < 10	Stop: < 50%	Stop: < 50%		Stop: < 50%	

IQR, interquartile range. HOA, hand osteoarthritis. N.a. not applicable.

Recruitment and retention

Effectiveness of recruitment was evaluated based on participant flow from referral to inclusion, randomisation and withdrawals. Retention was defined as completion of trial procedures, operationalised as participation in baseline and post-intervention trial assessments, regardless of intervention adherence. Recruitment and retention data were recorded consecutively in REDCap (32).

Acceptability of trial in practice

To evaluate the acceptability of trial procedures in relation to the predefined progression criteria, including randomisation and outcome assessment procedures, participants with HOA were asked two questions following baseline assessments and randomisation: 1) *How acceptable did you find the duration of the home visit?* 2) *How acceptable do you find the outcome of being placed on a waiting list or directly in a group through random allocation?* The questions were asked over telephone by the first author following baseline visit. Participants responded using a Numerical Rating Scale (NRS), ranging from 0 ("not at all") to 10 ("to a very high degree"). This approach was chosen to ensure standardised assessment of acceptability across participants.

Breadth and selection of outcomes

To assess the appropriateness of outcome measures for a future full-scale RCT, including whether selected outcomes appeared to be responsive and capable of capturing meaningful variation or change, outcome data were examined descriptively at the individual level.

Based on findings from the previous HANDY feasibility study (20), a three-day diary logbook was included as an exploratory outcome to capture real-time activity levels, activity patterns and pain at baseline and post-intervention trial assessments. The diary was structured according to the time-geographic method (34, 35). It was included to test the feasibility of this format and its administration procedures, as well as to explore whether the data provided sufficient descriptive information and variability, relevant for outcome selection in a future full-scale RCT. Appropriateness was evaluated based on completion rates and the extent to which diary data allowed an overall description of activity, patterns of tasks and pain experiences over time.

For the standardised outcome measures, appropriateness was explored by examining whether the selected instruments demonstrated individual-level variation and observable change between baseline and post-intervention assessments. This examination was undertaken to inform selection and prioritisation of outcomes and decisions regarding trial design for a future full-scale RCT, rather than to evaluate intervention effectiveness.

For the ADL-I and AMPS, established competence thresholds and reference values were used to support interpretation of outcome behaviour. For ADL-I (24), a change of > 0.66 logits was used as an indicative reference for meaningful variation in self-reported ADL performance, while for AMPS (26, 27) a change of > 0.3 logits in ADL motor and ADL process ability measures was used as a corresponding reference point. In AUSCAN pain, AUSCAN function and patient global assessment (36), a $\geq 20\%$ difference was considered clinically relevant (37). These thresholds were applied descriptively to examine whether the measures demonstrated sufficient individual-level variation and observable change to justify their use in a future trial.

Completion of measures

Completion of outcome measures was evaluated to assess feasibility of full data collection at baseline and post-intervention trial assessments. Outcome measures included the ADL-I (24), the AMPS (26, 27), European Quality of life 5 Dimensions (EQ-5D) questionnaire (38), Australian Canadian Osteoarthritis Hand Index (AUSCAN) questionnaire (39), patient global assessment measured by a visual analogue scale spanning from 0 (best) to 100 mm (worst) (40), and grip strength measured using the GRIPIT dynamometer (41). These outcome measures are commonly used in studies involving individuals with HOA, including the COLOR trial (42), and align with the core outcome domains recommended by the Outcome Measures in Rheumatology (OMERACT) initiative for HOA research (43).

The assessment focused on whether the selected outcome measures could be administered and completed as planned at both assessment time points. Completion was defined as participation in baseline and post-intervention trial assessments with no missing outcome measures at the person level.

Feasibility and acceptability in practice

To explore whether HANDY-OT was feasible and acceptable, occupational therapists and participants with HOA independently completed registration forms following each HANDY-OT session (week 1–6). Responses were recorded using ordinal scales ranging from 1 = 'to a very low degree' to 5 = 'to a very high degree' and "yes/no" categories. The questions replicated those used in the previous HANDY feasibility study (12) to examine whether feasibility and acceptability had improved following the refinement of the intervention (26, 39).

To evaluate intervention adherence, participation was monitored throughout HANDY-OT. Adherence was defined as participation in both individual sessions (session 1 and session 6) and at least three of the four group sessions. This definition reflects the minimum dose considered necessary to achieve a positive outcome. Data on adherence were collected using registration forms completed by participants with HOA and occupational therapists after each session, documenting attendance and reasons for absence.

Data handling

To ensure confidentiality, participants with HOA handed registration forms to the occupational therapist in closed envelopes at the end of each session. Data were entered into a secure database by the first author. The occupational therapists entered their questionnaire responses directly into REDCap.

Data analyses

Participant characteristics were summarised using descriptive statistics. Continuous variables were presented as medians and ranges due to non-normal distribution, while categorical variables were reported as numbers and percentages. Baseline characteristics for participants with HOA and occupational therapists were tabulated separately.

Recruitment and retention were analysed by calculating the number and percentage of participants referred, included, randomised, and completing baseline and post-intervention assessments, illustrated in a CONSORT-style flow chart. Acceptability of trial procedures was analysed using responses to two questions administered after baseline testing and randomisation, summarised as medians and interquartile ranges (IQR).

Appropriateness of outcomes and measurements was assessed by examining completion and descriptive quality of diary entries and evaluating whether the data provided sufficient detail to describe the participants' occupational patterns and pain experiences. Completion of outcome measures was analysed by calculating the percentage of participants completing all planned assessments at baseline and post-intervention. Progression criteria for completion of measures were defined as full completion of all planned assessments completed at both time points. Partial completion (e.g., missing individual items) was not analysed, as the aim was to evaluate feasibility of complete data collection in preparation for a future RCT.

Feasibility and acceptability of the intervention were analysed using ordinal data from registration forms completed by participants and occupational therapists after each HANDY-OT session. These data were summarised as medians and ranges. Intervention adherence was analysed by calculating the number and percentage of participants meeting the predefined adherence definition (participation in both individual sessions and at least three of four group sessions). Although no formal progression criterion was set for adherence, $\geq 80\%$ completion was considered acceptable.

Ethical

The study was conducted in accordance with the Helsinki Declaration and Danish law. Informed consent was obtained from each participant.

Results

The study included 32 participants with HOA. Baseline characteristics are summarised in Table 2. The median age was 77 years (range 59 to 94) and 72% were female. Half of the participants lived alone, whereas the other half lived with a partner and/or children. At baseline, participants reported mild to moderate ADL task performance problems, and demonstrated ADL ability below the AMPS ADL motor competence cutoff. The control group reported higher pain and stiffness on AUSCAN subscales. Other baseline variables were comparable between the groups.

Among the four occupational therapists, the median age was 42 years (range 28–52 years), with 75% being female. The median duration of their experience as occupational therapists was 11 years (range 1–23 years).

Table 2
Participants' baseline characteristics.

Gender Female n (%)	Total (n = 32)	Intervention (n = 16)	Control (n = 16)
	23 (72)	12 (75)	11 (69)
Age Median (range)	77 (59–94)	77 (62–94)	74 (59–90)
Civic status n (%)	16 (50)	10 (63)	6 (38)
Living alone	16 (50)	6 (37)	10 (62)
Living with a partner and/or children			
Job situation n (%)	1 (3)	0 (0)	1 (6)
Working	2 (6)	2 (12)	0 (0)
Unemployed / Homebound	1 (3)	0 (0)	1 (6)
Sick leave	28 (88)	14 (88)	14 (88)
Retired			
Educational level n (%)	7 (22)	6 (38)	1 (6)
Secondary school	6 (19)	3 (18)	3 (18)
Short term education	11 (34)	5 (32)	6 (38)
Medium term education	8 (25)	2 (12)	6 (38)
Higher education			
ADL-I performance median (percentiles)	1.5 (1.0–2.0)	1.9 (1.2–2.3)	1.3 (0.9–2.0)
ADL-I satisfaction median (percentiles)	1.8 (1.2–2.4)	1.8 (1.5–2.5)	1.5 (0.8–2.3)
AMPS ADL motor median (percentiles)	1.1 (0.9–1.4)	1.1 (0.9–1.5)	1.2 (0.8–1.4)
AMPS ADL process median (percentiles)	1.2 (0.8–1.4)	1.1 (0.7–1.4)	1.2 (0.9–1.4)
EQ-5D VAS median (percentiles)	70.0 (50.0–80.0)	70.0 (52.5–83.8)	72.5 (50.0–79.2)
AUSCAN pain median (percentiles)	34.3 (21.0–52.5)	28.8 (13.3–42.0)	45.9 (27.5–64.2)
AUSCAN stiffness median (percentiles)	43.0 (20.3–54.5)	38.5 (20.3–52.0)	48.0 (19.3–65.5)
AUSCAN function median (percentiles)	51.4 (35.9–67.4)	48.1 (33.9–66.6)	53.5 (43.3–78.5)
Patient Global health VAS median (percentiles)	65.0 (40.5–79.3)	65.0 (40.3–81.5)	62.0 (40.5–79.0)
Grip strength Newton (percentiles)	177 (108–282)	178 (108–283)	177 (116–291)

ADL-I Activities of Daily Living Interview; AMPS Assessment of Motor and Process Skills; EQ VAS European quality of life VAS; AUSCAN Australian Canadian Hand Osteoarthritis Index score. VAS: visual analogue scale.

Recruitment and retention

Between January and April 2025, 39 referrals were received across the two municipalities during the 10-week recruitment period (Fig. 3). Initial referral rates were low, and therefore additional recruitment strategies were incorporated. In Municipality A, occupational therapists delivering HANDY-OT identified potential participants among individuals with HOA who were already engaged in municipal rehabilitation services. Potential participants received information materials and were encouraged to contact their GP for a needs assessment and referral. In Municipality B, newspaper advertisements were made, which had a positive influence on the number of referrals; however, it necessitated an extension of the recruitment period with ten working days to accommodate delays due to the publication and subsequent GP appointments. The progression criterion was met, with amendments reflecting the extended recruitment timeline. All 32 participants (100%) were randomised to either the intervention or control group following baseline assessment.

Retention to trial procedures was high, with 29/32 participants (91%) completing post-intervention assessments, meeting the predefined progression criterion ($\geq 80\%$) (Details on intervention adherence are reported under Feasibility and acceptability of intervention).

Acceptability of the trial in practice

Study procedures were well accepted by participants, and progression criteria for trial procedures ($\geq 80\%$) were met with 100% compliance for randomisation and for completion of baseline and post-intervention assessments. Participants rated the duration of baseline home visit as highly acceptable (median = 10, IQR = 0) and the randomisation process, including allocation to either a waiting list or intervention group, was also rated as highly acceptable (median = 10, IQR = 2).

Breadth and selection of outcomes

Diary entries were received from 27 of 32 participants (84%) at baseline and from 16 of 29 participants (55%) at post-intervention trial assessment. The diary entries demonstrated considerable variation in the level of detail provided, which indicates that the format requires refinement before it can be used in a future full-scale RCT.

ADL tasks were generally documented in relation to specific times of day. However, descriptions of occupational patterns and pain experiences varied substantially across participants and timepoints. Furthermore, participants' identification numbers were not recorded consistently, which limited the ability to link diary data at the individual level between baseline and post-intervention. As a result, in their current form the diary data were insufficient to support individual-level comparisons of real-time activity patterns over time.

For the standardised outcome measures, individual-level variation and observable change were identified across baseline and post-intervention assessments. Using predefined descriptive reference thresholds, participants demonstrated heterogeneous patterns of outcome behaviour, including changes exceeding, approximating, or not reaching the reference values for meaningful variation. These patterns were observed in both the intervention and waiting-list control groups.

The observed heterogeneity in individual-level outcome behaviour indicates that the selected measures could capture meaningful variation and observable change at the individual level. These findings support the suitability of ADL-I and AMPS for use in a future full-scale RCT. The distribution of individual-level outcome behaviour relative to the predefined descriptive reference thresholds is illustrated in Fig. 4.

ADL-I Activities of Daily Living Interview; AMPS Assessment of Motor and Process Skills

Percentage distribution of participants demonstrating individual-level outcome behaviour relative to predefined descriptive reference thresholds for meaningful variation in ADL task performance. The figure illustrates the distribution of participants across outcome behaviour categories at baseline and post-intervention assessments for ADL-I and AMPS. The distributions are presented separately for the HANDY-OT and waiting-list control groups. The reference thresholds were applied descriptively to explore whether the selected outcome measures could capture meaningful variation and observable change at the individual level.

Completion of measures

Of the 29 participants eligible to participate in post-intervention tests, all evaluations were completed without missing data (Fig. 3) (except for the diary entries). Several participants indicated that the EQ-5D VAS and the Patient Global Health VAS were similar.

Feasibility and acceptability in practice

The participants with HOA and occupational therapists agreed that the content and delivery of HANDY-OT programme were relevant and worked well, with median ratings to a high to very high degree (median ≥ 4) (Table 3). Participants with HOA only to a fair degree felt that the homework assigned between session two and three supported progress toward their goals (median ≤ 3). Homework assignments after session three, four, and five, were rated to support progress toward goals to a high degree (median = 4).

Within the intervention group, 13/16 participants (81.3%) met the adherence definition, which was defined as participation in both individual sessions (sessions 1 and 6) and at least three of four group sessions. This indicates high adherence and supports feasibility of the intervention. Although no formal progression criterion was set for adherence, $\geq 80\%$ completion was considered acceptable. In Table 3, participation in sessions was presented based on the number of registrations completed by participants with HOA. Among the participants who completed HANDY-OT, five group session cancellations occurred (three due to scheduling conflicts, two due to illness). Nevertheless, all participants who completed HANDY-OT met the requirement for inclusion of attending at least three of four group sessions.

Table 3
Feasibility aspects based on registrations from participants with HOA (n = 14) and occupational therapists (n = 6).

		Sessions					
Session number		1	2	3	4	5	6
Number of registrations from participants with HOA, n(%)		14(100)	12(86)	14(100)	10(71)	11(79)	12(86)
Intervention development	(Re)evaluations (ADL-I and AMPS) provide insights into ADL task performance problems*	4(3–5)					4(3–5)
	Relevant discussions of session-specific themes*		4(3–5)	4(3–5)	5(4–5)	5(4–5)	
	The meeting contributed to the attainment of my goals*		4(2–5)	4(3–5)	4(3–5)	4(3–5)	4(4–5)
	Homework supports progress toward goals*			3(3–4)	4(3–5)	4(3–5)	4(1–5)
Perceived value, benefits, harms or unintended consequences	(Re)evaluations with the OT made sense*	5(4–5)					5(1–5)
	Discussing factors influencing ADL made sense*		4(4–5)				
	Practical peer learning activities in relation to the sessions theme made sense*		4(3–5)	4(3–5)	5(4–5)	5(4–5)	
	The group is a pleasant environment for discussions and peer exchanges*		4(4–5)	4(4–5)	5(4–5)	5(4–5)	
	The sessions have contributed to better handling of daily tasks*						4(4–5)
	I will continue to use the strategies I have learned in the sessions*						5(4–5)
Acceptability in principle	Satisfaction with the session*	5(4–5)	4(3–5)	5(3–5)	5(4–5)	5(4–5)	5(4–5)
Feasibility & acceptability in practice	I can see the purpose of participating*	5(4–5)	4(3–5)	4(4–5)	5(4–5)	5(3–5)	
Number of registrations from OTs, n(%)		14(100)	4(100)	4(100)	4(100)	4(100)	12(86)
		Individual	Group	Group	Group	Group	Individual
Intervention development	Insight into ADL problems for the individuals with HOA*	4(3–5)					
	Determined which ADL tasks and skills should be in focus for the group session*	5(4–5)					
	Dialogue about discrepancy worked well *	5(3–5)					
	Dialogue about GAS goals worked well*	4(2–5)					
	Presentation of session theme worked well *		4(3–5)	4(4–5)	4(4–4)	5(4–5)	
	Dialogue about session theme worked well *		5(4–5)	4(3–5)	4(2–4)	5(4–5)	
	Practical peer learning activities related to session theme worked well *		5(4–5)	5(4–5)	5(5–5)	5(4–5)	
	Session supported progress toward goals*		5(4–5)	5(4–5)	5(5–5)	5(2–5)	

		Sessions					
Session number		1	2	3	4	5	6
Perceived value, benefits, harms or unintended consequences	Session made sense for the individual with HOA*	4(4–5)	4(4–5)	4(4–5)	5(5–5)	5(3–5)	5(2–5)
	Overall, the occupational therapy intervention has supported progression towards goals*						4(3–5)
	Occupational therapy intervention has contributed to better ADL ability*						5(3–5)
	Believe that the individual with HOA will continue to use compensatory strategies*						5(3–5)
Acceptability in principle	Satisfied with delivery of the session*	5(4–5)	5(5–5)	5(4–5)	5(4–5)	5(5–5)	5(4–5)
	The individual with HOA was satisfied with the session*	5(3–5)	4(4–4)	4(4–5)	5(5–5)	5(3–5)	5(3–5)
	Content was suitable for group delivery*		5(4–5)	5(4–5)	5(4–5)	5(3–5)	

* Based on median and range of an ordinal scale: 1 = very low degree, 2 = low degree, 3 = fair degree, 4 = high degree, 5 = very high degree. HOA Hand Osteoarthritis; OTs Occupational Therapists; ADL-I Activities of Daily Living Interview; AMPS Assessment of Motor and Process Skills.

Discussion

The aim of this pilot and feasibility RCT study was to evaluate the feasibility of HANDY-OT v2.0 and to pilot key elements of trial design, including effectiveness of recruitment, randomisation, retention, acceptability of study procedures, and appropriateness and completion of outcome measures to determine whether predefined progression criteria were met. Overall, the pilot study met the predefined criteria for retention, acceptability of randomisation, and outcome assessment. Although amendments to the recruitment procedures were required to achieve the target sample size, the predefined recruitment criterion was ultimately met. The findings provide a structured basis for refining trial procedures, outcome selection, and study design in preparation for a future full-scale RCT. Furthermore, the intervention was perceived as feasible and acceptable by both participants with HOA and occupational therapists.

Recruitment and retention

Recruitment targets were achieved, although the inclusion period had to be extended in one municipality. This corresponds to the predefined progression criterion of ‘amend – proceed with changes’. Together, these findings provide important information regarding the feasibility of the recruitment procedures and indicate a need for flexibility in recruitment timelines in the planning of a future full-scale RCT.

Retention was defined as completion of trial procedures rather than intervention adherence, aligning with recommendations for feasibility studies (22). This distinction allowed evaluation of trial feasibility independent of intervention delivery and supported clearer interpretation of progression criteria.

Recruitment is often challenging and barriers such as strong treatment preferences, practical constraints, and clinical care pathways are commonly reported (44). These challenges were also evident in the present study, as HANDY-OT relies on cross-sectorial referral processes. In comparison, a pharmacological feasibility study in women with HOA screened 434 individuals to randomise only 28 participants (45). Against this backdrop, the HANDY-OT pilot RCT appears comparatively efficient, supported by realistic inclusion criteria and a targeted recruitment strategy.

Offering the control group access to HANDY-OT may have facilitated recruitment by reducing reluctance to randomisation. However, this strategy has implications for the future trial design and resource allocation. Maintaining a waiting-list model in a full-scale RCT will require additional planning to ensure timely delivery of the intervention after the trial period. From a feasibility and planning perspective, this approach increases the overall duration of the study and demands additional therapist time and organisational resources, which should be reflected in the budget. Furthermore, it may influence long-term outcome measurement, as participants in the control group will eventually

receive the intervention, limiting the ability to assess sustained between-group differences. Alternative designs, such as a parallel-group RCT without post-trial intervention or a stepped-wedge design (46), should therefore be considered and weighed against ethical and practical concerns.

Nevertheless, planning for a future full-scale RCT should include strategies to strengthen recruitment and allow for extended inclusion period, where needed. Positive experiences from this pilot RCT provide insights into how potential participants can be identified to facilitate timely recruitment. In future RCT studies, alternative organisational strategies, newspaper advertisements and personal approaches during other sessions at the municipal rehabilitation centre may be relevant recruitment supplements. These methods showed a positive impact on participant flow in this study. Furthermore, based on experiences from this pilot study, involving the municipality's training coordinator as part of the stakeholder group appears to be an effective and context-specific strategy for identifying potential participants during the recruitment process.

Retention to trial procedures was high (91%) and intervention adherence was also acceptable (81%). Still, in a future RCT, adherence requirements may need refinement, e.g., reducing mandatory sessions or offering flexible formats to accommodate transportation and health-related barriers. The distinction between retention and adherence remains important: retention reflects trial feasibility, whereas adherence informs intervention feasibility and potential effectiveness.

Randomisation and baseline difference

Randomisation to either intervention or waiting list was highly acceptable for the participants, this presumably reflects trust in healthcare professionals and satisfaction with the information provided. Such factors are known to facilitate engagement in RCTs (47). Overall, baseline variables were comparable between the groups. However, a previous study of participants with chronic conditions has suggested a need for stratified randomisation based on AMPS ADL motor ability measure as implemented in the ABLE RCT (48) to ensure balanced allocation.

Overall, the retention was acceptable, although three participants withdrew after randomisation to the intervention group. These participants actively declined further participation and were therefore not offered post-intervention assessments, which differs from standard RCT practice, in which follow-up is typically encouraged even for dropouts. Reasons for withdrawal included hearing and/or cognitive challenges ($n = 1$), and transportation barriers ($n = 2$). For a future full-scale RCT, it is recommended to offer follow-up assessments to participants who discontinue the intervention to strengthen retention to trial procedures and to reduce the risk of bias. In addition, strategies to address transportation barriers and consider alternative formats for individuals with hearing and/or cognitive challenges should be explored, as these factors may influence feasibility of group-based delivery. This highlights the need for careful attention to inclusion criteria and logistical support in HANDY-OT.

Outcome measures

The high completion rate for outcome measures demonstrated that the selected instruments were feasible to administer and complete as planned within the context of this pilot study, supporting their use in a future full-scale RCT. Furthermore, the examination of individual-level outcome behaviour indicated that the selected measures captured meaningful variation and observable change over time, which is a prerequisite for informed outcome selection and trial design.

However, methodological challenges were identified for the diary entries. Progression criteria were deliberately not applied to diary entries, as these were included to explore feasibility of the format and procedures as part of trial preparation. Participants were asked to complete a three-day diary following baseline and post-intervention visits and return it by post. However, response rates were low at post-intervention and entries varied in detail. These findings indicate that the current diary format and data collection procedures are not sufficiently robust for use in a future full-scale RCT without modification.

For a full-scale RCT, alternative and more efficient data collection methods should therefore be considered to improve response rates, rather than relying on return envelopes for mailing the diaries. In addition, the diary format requires revision to ensure participants' IDs are recorded and that entries consistently capture occupational patterns and pain experiences as intended (34, 35). Digital data collection solutions, such as REDCap (32), may offer a more feasible approach, as they allow participants to complete their diary entries through structured online surveys that are accessible via mobile devices or computers. Such solutions could support improved data quality through mandatory fields (e.g., participant ID), structured response options, and automated reminders, and have been applied successfully in previous studies using time-geographic approaches (49, 50). However, given the age group and potential digital literacy challenges, future studies should consider providing technical support or offering hybrid options (paper and digital) to accommodate participant preferences.

In the present study, outcome assessments were limited to baseline and post-intervention. From a trial design perspective, this timing provides information on short-term outcome behaviour but limits insight into whether observed changes are sustained over time. Evidence from previous trials that have evaluated occupational therapy interventions targeting ADL performance suggests that meaningful differences may not be detectable immediately post-intervention but may emerge at later follow-up assessments. For example, in the ABLE RCT (48) no statistically significant or clinically relevant differences between groups were observed immediately post intervention for either self-reported ADL task performance (ADL-I) or observed ADL motor ability (AMPS). However, the inclusion of 26-week follow-up revealed a statistically significant and clinically relevant difference in AMPS ADL motor ability in favour of the intervention group.

These findings illustrate the importance of incorporating follow-up assessments in trials evaluating adaptational occupational therapy interventions, where changes in task performance may require time to consolidate and be reflected in observed ADL ability. Accordingly, inclusion of follow-up assessments in a future full-scale RCT of HANDY-OT would strengthen the ability to distinguish short-term variation from more sustained outcome patterns and to support robust interpretation of intervention-related change.

Participants in this study reported that the wording of the Patient Global Health VAS (40, 43) did not clearly differ from that of the EQ-5D VAS (38), suggesting potential overlap. This finding provides useful information for outcome selection, indicating that, in a future RCT, it may be relevant to consider alternative instruments that more clearly capture the specific impact of HOA on overall health status, or to omit one of the measures to reduce respondent burden.

Feasibility of HANDY-OT (v2.0)

Overall, the revised HANDY-OT intervention was perceived as highly relevant by both participants with HOA and occupational therapists. This supports the feasibility and acceptability of HANDY-OT in practice. The intervention emphasises peer interaction as a means for developing problem-solving skills targeted at participants' ADL goals. This approach aligns conceptually with the principles of the Chronic Disease Self-Management Program (CDSMP) (51), advocating peer learning based on self-defined needs and goals to manage symptoms such as pain and fatigue when living with chronic conditions. While CDSMP focuses on symptom management (51), HANDY-OT applies similar principles addressing ADL tasks performance problems. Comparable findings have been reported in an occupational therapy group-based intervention for individuals with fibromyalgia, where peer-to-peer interaction was described as an important mechanism for achieving desired outcomes (19).

Positive perceptions of HANDY-OT may also relate to stakeholder involvement during development of HANDY management programme. Close collaboration with stakeholders enabled translation of the evidence-based intervention process model OTIPM (24) and research-supported methods (14, 17, 18, 29) for individuals with HOA into a group-based intervention that seem to add value to municipal rehabilitation practice. Using an evidence-informed framework, while considering the clinical context has been emphasised as a key principle for coherent delivery of interventions in health care organisations (52). Furthermore, a review of peer interaction in patient education identified psychological factors (bonding, safety, humour), environmental factors (access to information, sufficient time), and relational factors (continuity and personalised support) as critical for success (53). These factors were also highlighted by participants during the development of the HANDY management programme (20) and are represented in their responses (Table 3), which indicates that the two-hour group sessions largely succeeded in meeting these needs.

Homework assignments remained a challenge in HANDY-OT v2.0 and were not consistently rated as effective in supporting goal setting. Dewey's theory of practical experiential learning (54) emphasises that performing tasks and reflecting on experiences are essential for applying new knowledge. Findings from the present study, supported by insights from the ABLE realist evaluation (55), suggest that homework assignments should be redesigned to ensure relevance and generate active engagement. Specifically, tasks should be individualised, linked to participants' goals, and supported by clear, visual instructions and structured reflection prompts. Future studies should consider integrating feedback mechanisms and digital support tools (e.g., mobile apps or online platforms) combined with reminders and short instructional videos to enhance the clarity of the assignment and adherence. Insights from the ABLE process and realist evaluations (56) highlight that supported practice in the home, combined with observation-based feedback and dialogue with the occupational therapist, is central to integrating new strategies into individuals everyday routines. This suggests that homework assignments should prioritise guided practice and reflection rather than unsupervised activities.

Strengths and limitations

This pilot RCT demonstrated several methodological strengths. Recruitment, randomisation, and retention largely met the predefined progression criteria, which support the feasibility of the trial design. Completion rates for outcome measures were high, which suggests that the selected instruments are appropriate for a full-scale trial. Furthermore, participants rated randomisation and trial procedures as highly acceptable, likely supported by clear communication and trust in healthcare professionals.

Several limitations should be noted. Recruitment required an extended inclusion period and additional strategies, such as GP engagement and advertising, highlighting the need for predefined supplementary strategies and longer recruitment windows in future trials. Furthermore, retention issues, including withdrawals linked to hearing and cognitive challenges and transportation barriers, underline the importance of refining eligibility criteria and addressing logistical constraints.

Progression criteria were deliberately not applied to the remaining feasibility aspects, which were explored qualitatively. Methodological challenges were noted for diary entries; these were included with the sole purpose of assessing the feasibility of the format, not intervention effects. Future trials should revise the diary format and consider digital solutions to improve compliance. Moreover, participants also perceived an overlap between EQ-5D VAS and Patient Global Health VAS, suggesting that alternative instruments may be more suitable for capturing the specific impact of HOA on overall health status. Finally, home-based assessments were resource-intensive; completing these within a one-week testing window would require careful planning or alternative formats in a full-scale RCT.

Conclusion

This pilot study demonstrated that key elements of trial design, including recruitment, randomisation, retention, and outcome assessment, met the predefined progression criteria, supporting feasibility. Outcome measure completion was high, and trial procedures were well accepted by participants. Furthermore, HANDY-OT v2.0 was perceived as feasible and acceptable to a high degree by both participants with HOA and occupational therapists. These findings indicate that a full-scale RCT is justified, provided that recruitment strategies are refined and diary procedures are improved.

Declarations

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Consent for publication: Not applicable

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Figures

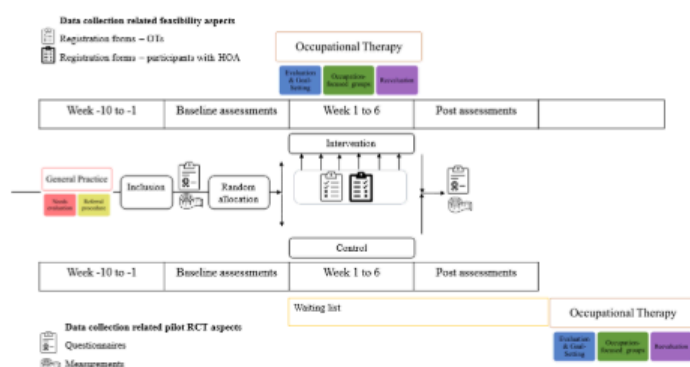


Figure 1

The pilot and feasibility study design.

HOA, hand osteoarthritis. OTs, occupational therapists. RCT, randomised controlled trial.

SCREENING FOR HOA		
Check 'Yes' or 'No' for each item.		
If at least one 'Yes' → Referred to occupational therapy		
Item	YES	NO
1. Decreased grip strength (assessed by GP handshake)		
2. Problems turning things with the hands, e.g. turning a key in a lock or a rounded doorknob		
3. Problems peeling vegetables or fruit		
4. Problems picking up big heavy things		
5. Problems wringing a washcloth or dishcloth		
6. Problems buttoning buttons		

Figure 2

HANDY (v.2.0) needs evaluation.

HOA, hand osteoarthritis. OTs, occupational therapists.

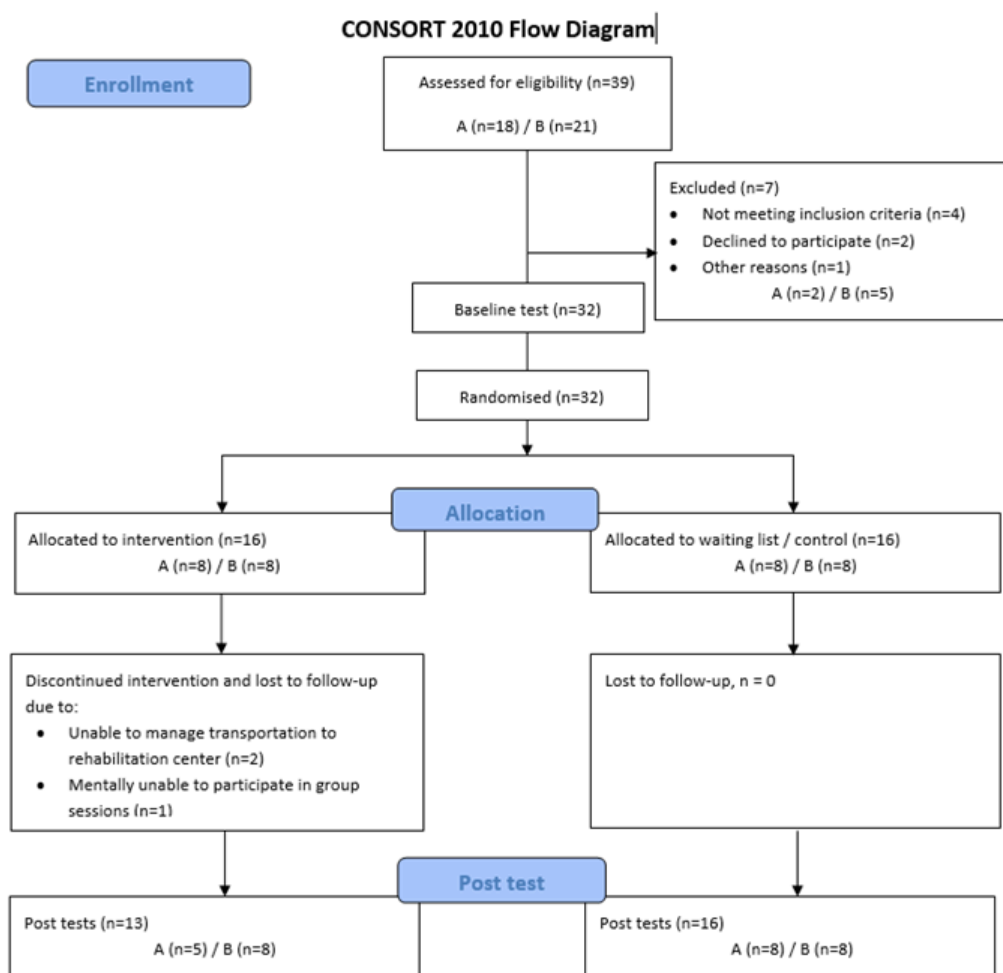


Figure 3

CONSORT diagram for inclusion. A and B refer to the different municipalities.

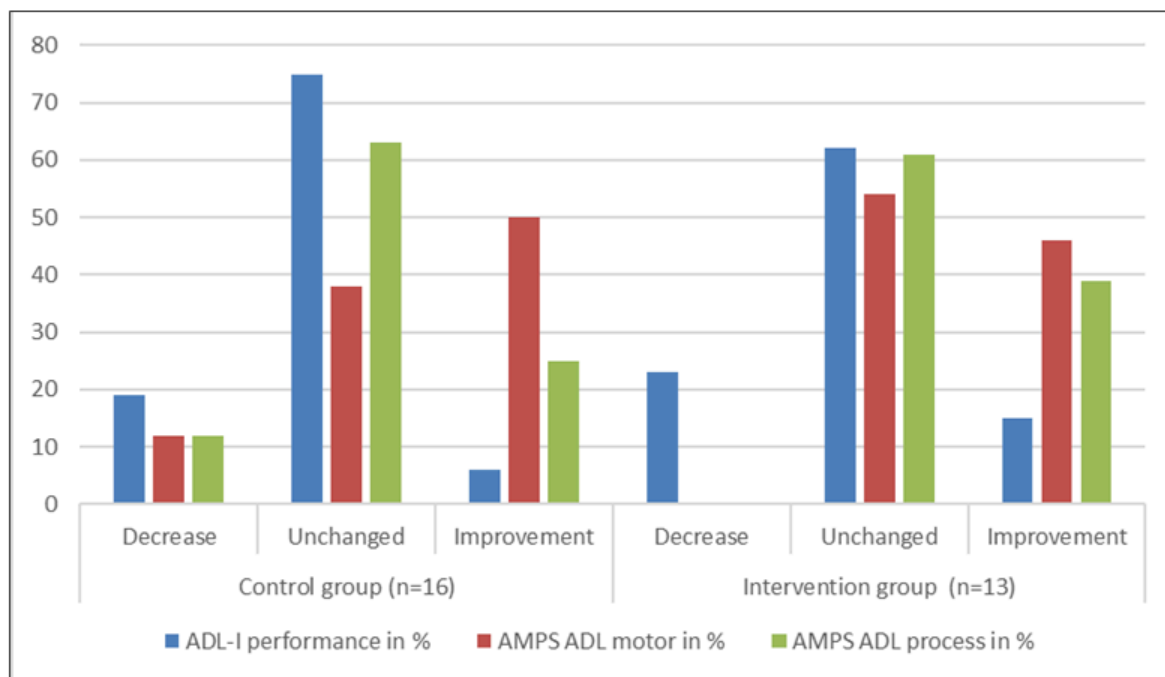


Figure 4

Distribution of individual-level outcome behaviour relative to predefined reference thresholds

ADL-I Activities of Daily Living Interview; AMPS Assessment of Motor and Process Skills

Percentage distribution of participants demonstrating individual-level outcome behaviour relative to predefined descriptive reference thresholds for meaningful variation in ADL task performance. The figure illustrates the distribution of participants across outcome behaviour categories at baseline and post-intervention assessments for ADL-I and AMPS. The distributions are presented separately for the HANDY-OT and waiting-list control groups. The reference thresholds were applied descriptively to explore whether the selected outcome measures could capture meaningful variation and observable change at the individual level.