

ORIGINAL ARTICLE

A client-centred ADL intervention: three-month follow-up of a randomized controlled trial

ANN-SOFIE BERTILSSON^{1*}, MARIA RANNER^{1*}, LENA VON KOCH^{1,2},
GUNILLA ERIKSSON^{1,3}, ULLA JOHANSSON^{1,4}, CHARLOTTE YTTERBERG¹,
SUSANNE GUIDETTI^{1,5} & KERSTIN THAM^{1,5}

¹Department of Neurobiology, Care Sciences and Society, Karolinska Institutet, Stockholm, Sweden, ²Department of Neurology, Karolinska University Hospital, Stockholm, Sweden, ³Department of Speech Pathology, Physiotherapy and Occupational Therapy, University Hospital, Uppsala, Sweden, ⁴Department of Development and Research, County Council of Gävleborg/Uppsala University, Gävle, Sweden, and ⁵Department of Occupational Therapy, Karolinska University Hospital, Huddinge, Sweden

Abstract

Objective: The aim was to study a client-centred activities of daily living (ADL) intervention (CADL) compared with the usual ADL intervention (UADL) in people with stroke regarding: independence in ADL, perceived participation, life satisfaction, use of home-help service, and satisfaction with training and, in their significant others, regarding: caregiver burden, life satisfaction, and informal care. **Methods:** In this multicentre study, 16 rehabilitation units were randomly assigned to deliver CADL or UADL. The occupational therapists who provided the CADL were specifically trained. Eligible for inclusion were people with stroke treated in a stroke unit ≤ 3 months after stroke, dependent in ≥ 2 ADL, not diagnosed with dementia, and able to understand instructions. Data were collected at inclusion and three months thereafter. To detect a significant difference between the groups in the Stroke Impact Scale (SIS) domain “participation”, 280 participants were required. Intention-to-treat analysis was applied. **Results:** At three months, there was no difference in the outcomes between the CADL group ($n = 129$) and the UADL group ($n = 151$), or their significant others ($n = 87/n = 93$) except in the SIS domain “emotion” in favour of CADL ($p = 0.04$). **Conclusion:** The CADL does not appear to bring about short-term differences in outcomes and longer follow-ups are required.

Key words: stroke, rehabilitation, participation, occupational therapy, multicentre study, lived experience, goal setting, everyday occupation, caregiver, activity

Introduction

In the present study, a new client-centred activities of daily living (ADL) intervention (CADL) after stroke was evaluated based on the CONSORT guidelines (1). The term client-centred implies an intervention tailored to the client’s ability and perceived needs, which takes the client’s lived experiences (2) as the point of departure. Since stroke has proved to cause restrictions in everyday life for both the person with stroke and

significant others, the definition of client includes the significant others, e.g. partners, sons, daughters, or friends and ADL encompasses all everyday activities that a person wants and needs to perform (3).

Despite national guidelines for stroke care (4) and access to rehabilitation services, people with stroke experience dependence in ADL and restrictions in participation (5,6). Participation is an important concept and outcome in the field of rehabilitation (3,7). Two dimensions of participation are referred

Correspondence: Susanne Guidetti, Department of Neurobiology, Care Sciences and Society, Karolinska Institutet, Division of Occupational Therapy, Fack 23200, 141 83 Huddinge, Sweden. E-mail: susanne.guidetti@ki.se

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to in this study. The first dimension is participation, according to the International Classification of Disability and Health (ICF) (8), defined as a person's involvement in a life situation and the second dimension is participation in everyday occupations incorporating the term "occupations", which is defined as groups of activities of everyday life that are given value and meaning by the individual (9). Participation is perceived to be restricted three months after stroke even among persons who are highly recovered (10). One can therefore assume that participation is an important goal for new rehabilitation interventions and should be evaluated continuously during the client's recovery process (5).

Frequent use of informal care in ADL is common and significant others have reported experience of constraint in their life situation (6,11). As functioning in ADL is also known to be associated with perceived life satisfaction among people with stroke and their significant others (12-14), there is a strong incentive to develop ADL interventions that better enable independence and participation in everyday occupations after stroke, which may also contribute to a lower caregiver burden on significant others.

There is a lack of well-defined, scientifically evaluated ADL programmes (15,16). Research has defined different therapeutic strategies, important with regard to client-centred ADL interventions. Key concepts in client-centred practices are individual autonomy and choice, partnership, the therapist's and the client's responsibility, as well as enablement.

The interventions should meet the person's goals and resources, and provide specific training in the activities in which the person wants and needs to be engaged (17-19). A fundamental concept in occupational therapy is to create opportunities to practise and experience the performance of everyday occupations (20) in close collaboration with the occupational therapist (OT) who gradually assists the person to assume autonomy in decision-making and action (21). Previous randomized controlled trials (RCT) of home rehabilitation after stroke support the assumption that client involvement (22) in the rehabilitation process may have a superior effect on ADL functioning both during the first year after stroke (23) and five years after the intervention (24).

When developing complex interventions, the use of qualitative studies is recommended in order to understand clients' experiences and the change mechanisms underlying the intervention (25). Findings from a series of qualitative studies (26-30) of the lived experiences of people with stroke have unveiled a need to develop an ADL intervention that takes its point of departure in the client's lived experiences (2). By creating a relationship based on trust, the OTs can use their empathetic understanding to

better understand the client's lived experiences, which is a prerequisite for supporting the clients to formulate goals for their intervention (24-28). To meet this requirement, a client-centred ADL self-care intervention was developed and evaluated in a pilot study showing that the study design and method were, with some modifications, suitable for a full-scale RCT (31,32). Since the intervention comprises the core aspects of client-centred interventions and takes its point of departure in the client's lived experiences (2), the intervention was modified to include all activities that the client needed and wanted to perform in everyday life.

Some empirical studies that support a client-centred approach and the use of everyday occupations in occupational therapy (33) do exist, but further evaluations of client-centredness are warranted (34). Thus, there is a need for clinical trials that might contribute to exploring and evaluating the effects of client-centred ADL interventions for both persons with stroke and their significant others compared with the usual ADL interventions (UADL). The long-term goal of the CADL is to enable agency in activities and participation in everyday life among persons with stroke. According to Aarts and colleagues (35), independence in ADL is of importance for a person's sense of agency in daily life, i.e. the feeling that one causes one's own actions and their outcomes. Townsend and Laundry (36) also outlined that the recognition of persons as active agents is of importance in interventions aiming to enable participation in everyday occupations.

The aim was to study the effects of the CADL compared with UADL three months after the start of the interventions in people with stroke and their significant others. At three months the interventions were expected to have just been completed and this is also a point in time when people with stroke are known to experience restrictions in participation (10). The hypotheses were that people with stroke who receive the CADL will be less dependent on assistance in ADL, perceive less restriction in participation, and have higher life satisfaction than those who receive UADL. A second set of hypotheses was that the significant others of people with stroke who receive the CADL will perceive lower caregiver burden and higher life satisfaction than the significant others of those who receive UADL after stroke. The aim was also to study the effects on the use of home-help service, satisfaction with training, and provision of informal care. The aim was, thus, to study the effects of CADL compared with UADL three months after the start of the interventions in: (I) people with stroke regarding: (a) independence in ADL, (b) perceived participation, (c) life satisfaction, (d) use of home-help service and satisfaction with training, and (II) the significant others of persons with stroke receiving

CADL or UADL regarding: (a) caregiver burden, (b) life satisfaction, and (c) provision of informal care.

Material and methods

Trial design and participants

This study was a multicentre RCT with an intervention group receiving the CADL and a control group receiving UADL. Rehabilitation units in Stockholm, Uppsala, and Gävleborg County Councils, to which the people with stroke were referred for rehabilitation from stroke units, were asked to participate in the study. Sixteen rehabilitation units agreed to participate. The units represented inpatient and outpatient home-based rehabilitation.

Eligible for inclusion in the study were people who were: (a) treated for acute stroke in a stroke unit ≤ 3 months after stroke onset, (b) dependent in at least two ADL domains according to Katz Extended ADL Index (KE) (37), (c) not diagnosed with dementia, (d) able to understand and follow instructions, and (e) referred for rehabilitation to one of the 16 participating units.

Interventions

Content of the CADL. The CADL intervention integrated the principles of client-centred practice (17) and the person's unique lived experiences for goal setting and collaboration during the rehabilitation process. A basic assumption for the CADL was that people develop skills and knowledge by having experiences linking their past experiences in everyday life (2) to their future horizons. CADL included nine steps (31,32) and significant others were invited to participate during the rehabilitation process. The first step of the CADL was to create a relationship between the OT and the person with stroke, which was seen as a prerequisite for understanding the person's life-world experiences. Next, the OT observed the client performing an activity and then together they evaluated the performance in order to clarify the client's ability and perceptions of his/her ability. By using the Canadian Occupational Performance Measure (38), the client identified three goals for activities he/she wanted and needed to perform. After learning a global problem-solving strategy, i.e. a goal-plan-do-check strategy inspired by Polatajko and colleagues (39), the client performed the activity ranked as the first goal to discover and identify difficulties in reaching the goal. Thereafter, the client and the OT together identified specific strategies that would enable successful performance of the chosen activity. Different strategies were used for problem solving, e.g. implementing new ways of performing ADL; modifying the environmental demands. The client learned how to use

a training diary in order to communicate with others involved in the rehabilitation. In the last session, the OT and the client reviewed all strategies utilized during the sessions in order to facilitate transfer of learning to activities and situations outside therapy.

The OTs who carried out the CADL intervention in the study were taught the CADL in a five-day workshop (four days distributed over a one-month period and a one-day follow up one month later) by the researchers (GE, UJ, CY, SG).

Content of the UADL. Participants who were admitted to rehabilitation units randomized to supply the UADL – the intervention received by the control group – did not receive one specific intervention but rather a variety of strategies and ways to conduct customary ADL intervention. The UADL intervention varied in extent and methodology according to the routines and practices of the OTs at the participating rehabilitation units.

The number of occupational therapy sessions was not limited or decided in advance for either group. All participants with stroke in the study, both in the CADL and in the UADL group, received other rehabilitation services as needed, e.g. physiotherapy and speech therapy. To facilitate participation and to ensure adherence to the design of the study the researchers (GE, UJ, CY, SG) contacted all the OTs engaged in both the CADL and UADL rehabilitation regularly.

After informed consent was obtained, people with stroke who met the inclusion criteria were assessed by a data collector at the rehabilitation unit. In addition, the participants with stroke were asked to name a significant other, e.g. partner, son, daughter, or friend, who was contacted and asked to participate in the three-month follow-up. For each participant, the same data collector carried out data collection at baseline – inclusion in the study – and at three months thereafter. The researchers (GE, UJ, CY, SG, LvK) developed protocols for data collection from the participants with stroke and from the significant others. To ensure that the data collection was conducted in a similar way, all data collectors were trained in the data-collection procedure. The researchers (GE, UJ, CY, SG) had regular meetings with the data collectors and were available when they needed to discuss any questions arising. The data collectors had regular contacts with the participating units in order to be updated on new persons eligible for inclusion in the study.

Data collection

The participants' medical history was obtained from their medical records and by means of interview. Demographic data on the participants with stroke

and their significant others were collected by interview. The remaining data were collected at baseline and at three months by frequently used instruments validated for people with stroke and in Sweden.

At baseline, the Mini-Mental State Examination (MMSE) (40) was used for screening of cognitive function. Speech production was categorized according to the Scandinavian Stroke Scale (41): “no aphasia”, “limited vocabulary”, “more than yes/no”, or “only yes/no or less”. A modified item from the Scandinavian Stroke Scale was used to categorize the participants’ gait capacity: “unable to walk”, “walks with aid and help of another person”, “walks with aid” or “walks 5 m without aids”.

Outcomes - participants with stroke

Independence in ADL. The KE (37,42) was used to assess self-reported capacity in six essential, personal ADL (PADL) and four instrumental ADL (IADL). The KE was trichotomized into either “independent in both”, “independent in P- or I-ADL”, or “dependent in both”. Reliability and validity of the instrument have been found to be satisfactory (37,42).

The Barthel Index (BI) (43) was used to assess independence/dependence in ADL. The BI measures independence in 10 self-care and mobility activities. Scores range from 0 to 100, with a lower score indicating greater dependency. Stroke severity at inclusion in the study was categorized based on the BI scores <15 = severe, ≥15–49 = moderate, ≥50–100 = mild (44). BI has been reported to be reliable and valid for people with stroke (45–47).

Perceived participation. The primary outcome was perceived participation, which was assessed using the Stroke Impact Scale 3.0 (SIS) (48), domain eight, “participation”. All other outcomes were secondary outcomes. The SIS (48) measures the perceived impact of stroke and consists of 59 items forming eight different domains. The SIS scores range from 0 to 100 and the greater the score, the less the impact. The SIS was administered to the study participants at the three-month follow-up and a proxy version (49) was used when appropriate. The perceived recovery was measured at baseline and at the three-month follow-up on a visual analogue scale from 0 to 100. Zero indicates no recovery and 100 full recovery (48). The SIS has been shown to be reliable, valid, and sensitive to change (48).

The Occupational Gaps Questionnaire (OGQ) (50) was used to assess perceived participation in everyday occupations. A gap or a restriction in participation is considered to be present when there is a discrepancy between what the individual wants to do

and what he or she actually does. The OGQ is a checklist comprising 28 activities regarding instrumental ADL, work or work-related activities, leisure and social activities. For each activity there are two questions: (a) if the person performs the activity (yes/no) and (b) if the person wants to perform the same activity (yes/no). When there is a discrepancy between the responses to the two questions, an occupational gap is considered to be present. An optimal outcome is the absence of gaps. The OGQ is a valid measure across different groups (50).

Life satisfaction. The Life Satisfaction Scale (LiSat-11) (51) assesses overall and domain-specific life satisfaction in 11 items. To assess the participants’ overall satisfaction with life, one global question in the LiSat-11 was used. LiSat-11 uses a six-step, ordinal, self-rating scale ranging from (6) “very satisfied” to (1) “very dissatisfied”. For the analysis, the score for the item was dichotomized into satisfied = yes (score 5–6) or not satisfied = no (score 1–4). The LiSat-11 has been shown to have acceptable test–retest reliability, specificity and sensitivity (51).

Home-help service and satisfaction with training

Information about home-help service (yes/no) was self-reported by the participant with stroke. One statement from a questionnaire based on a taxonomy developed by Ware (52) was used to reflect met/unmet need for training: “I have received the training that my condition has required” rated on an ordinal self-rating scale ranging from “fully agree” (1) to “do not agree at all” (5). In the analysis, the score for the item was dichotomized into agree = met need (score 1–2) or do not agree = unmet need (score 3–5).

The aim of the intervention was not to reduce falls but since there is an increased risk of falls after stroke, self-reported information about falls (yes/no) since inclusion in the past three months was collected to monitor the safety of the intervention.

Outcomes – significant others

Caregiver burden. All data regarding significant others were collected at three months. The Caregiver Burden Scale (CBS) (12) was used to assess caregiver burden. The CBS consists of 22 items for different types of subjective caregiver burden, covering areas of the caregiver’s health, feelings of psychological well-being, relations, social network, physical workload, and environmental aspects. The items are scored on a scale from 1 to 4 and the higher the score the greater the burden. The scale has been shown to have good construct validity and test–retest stability (12).

Life satisfaction and perceived participation in everyday occupations. LiSat-11 (51) was used to assess the overall life satisfaction of significant others and the OGQ (50) to assess their perceived participation in everyday occupations.

Informal care. Information on unsalaried, informal care by the significant others was collected (yes/no). The significant others were asked if there were any ADL in which the participant had needed his/her assistance or supervision that, prior to stroke onset, had been performed independently by the participant.

Duration and content of intervention received

Information regarding the length of rehabilitation, i.e. the number of days at the rehabilitation unit or days with home rehabilitation, and the participants' number of occupational therapy contacts as well as their content was collected from the OTs' records. When classifying the content of the occupational therapy contacts, predefined categories set by the researchers were used based on the conceptual terminologies of The Swedish Association of Occupational Therapists (FSA-Föreningen Sveriges Arbetsterapeuter) (53). Each occupational therapy contact might contain one or several foci, e.g. training in daily activities and evaluation of the environment. After all the participants were included in the study, a questionnaire was sent out to the participating rehabilitation units in order to collect information regarding staff turnover and number of people with stroke admitted during one year.

Sample size

A power calculation was performed based on the variance in the pilot study (32) and on a difference of 15 points in the SIS domain eight, "participation", as it has been suggested that it may represent a clinically meaningful change (48). Allowing for a 20% dropout rate, 280 people with stroke were included (alpha set at 0.05 and beta at 0.80).

Randomization sequence generation/implementation

The units were randomized, stratified by type of rehabilitation, inpatient geriatric rehabilitation, inpatient medical rehabilitation for persons <65 years, and home-based rehabilitation. A researcher coordinated the study for each county council (GE, UJ, CY, SG).

Blinding

The data collectors were not acquainted with the content of the interventions and were blinded to which type of intervention was delivered by which site.

Statistical methods

Descriptive statistics were used to present the characteristics of the participants and the outcomes at three months. All statistical analyses comparing the outcomes at three months of the UADL and the CADL groups were performed as intention-to-treat, including all participants. For missing values, the imputation method of last value carried forward was applied or the worst value of the study population at three months for variables not collected at baseline was used.

Statistical analyses of differences between the CADL and the UADL groups at three months were performed with univariate analyses of variance for the SIS, the OGQ, and the BI and multinomial/binomial logistic regression analyses for the KE, the Lisat-11, home-help service, the participants' satisfaction with training, and fall incidence. Regarding significant others, univariate analyses of variance were performed for the CBS and the OGQ and multinomial/binomial logistic regression analyses for the Lisat-11 and information regarding performance of informal care.

Covariates included in all statistical analyses for the participants were: sex, age, stroke severity, type of rehabilitation (geriatric, medical, or home rehabilitation), and independence/dependence in ADL before stroke according to KE. In addition, SIS recovery at baseline was included as covariate in the analyses of SIS recovery at three months. The covariates used in the statistical analysis for the significant others were: sex of the significant other, age of people with stroke, stroke severity, type of rehabilitation, and independence/dependence in ADL at three months according to KE. Additional analyses with the variable "cohabiting" included as a covariate were performed. The results were, however, similar and the results are thus presented without "cohabiting" as a covariate. A *p*-value of < 0.05 was accepted as statistically significant. The statistician was blinded to which group had received which intervention. The analyses were conducted using SAS (Science Analysis System) and SPSS (Statistical Package for the Social Sciences).

Results

Flow and baseline data

Participant flow is illustrated in Figure 1. Between 6 October 2009 and 7 September 2011, 280 people

with stroke were recruited to the study. In total, there were 44 OTs, who were trained in six different sets of CADL workshops during the study, and approximately 55 OTs were involved in the study to provide the UADL intervention. The length of rehabilitation, the number of occupational therapy contacts, and the focus of the occupational therapy sessions up to three months after inclusion in the study are presented in Table I. The results show that the CADL group received more occupational therapy than the UADL

group. At three months, most participants were discharged from the rehabilitation units. The range of participants admitted to the 16 participating rehabilitation units during one year was from fewer than 25 to more than 200 in the different units. The mean duration of rehabilitation for people admitted to the participating units (during three months) was 40 days, range 7–90 days.

Baseline characteristics of the participants with stroke are presented in Table II.

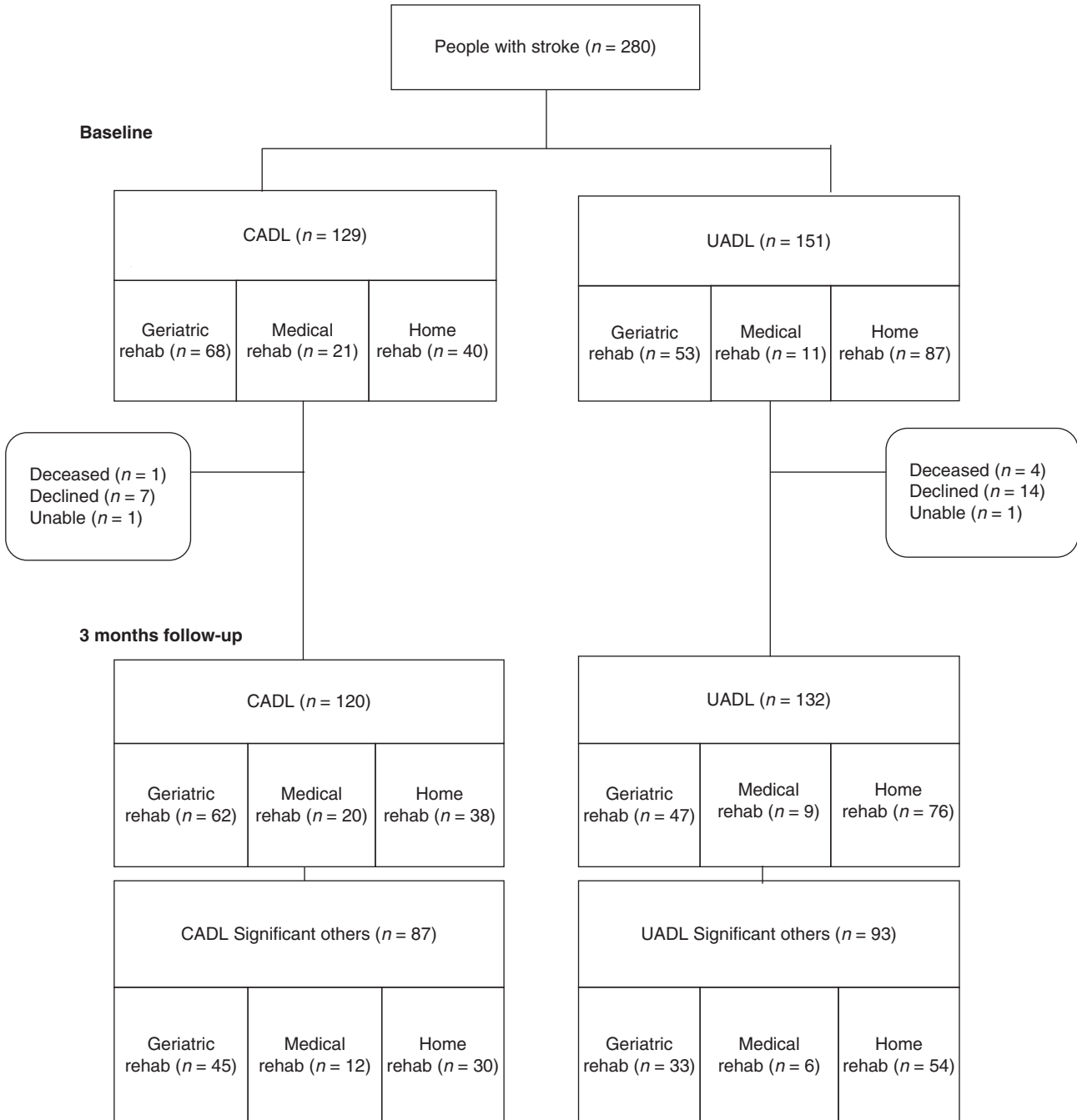


Figure 1. Participant flow from baseline to three-month follow-up.

Table I. Occupational therapy contacts for the CADL and the UADL groups up to three months after inclusion.

		Group CADL (n = 129)	Group UADL (n = 151)
Treatment period, days	Mean (range)	53.9 (7–90)	45.0 (1–90)
Occasions/contacts* between the OT and the participant, n		19.3 (1–52)	13.4 (1–91)
OT administration (without the participant), n		3.6 (0–13)	3.2 (0–13)
Occasions/contacts total*, n		21.9 (1–61)	15.7 (1–91)
Focus of contacts:			
Goal setting, planning and evaluation*, n		2.7 (0–12)	1.3 (0–5)
Activities of daily living*, n			
– self care		6.2 (0–22)	3.4 (0–26)
– mobility		3.2 (0–26)	2.5 (0–25)
– domestic life		5.0 (0–20)	2.8 (0–14)
– work		0.2 (0–2)	0.3 (0–2)
– leisure		2.5 (0–19)	2.9 (0–43)
– communication about ADL		2.7 (0–13)	1.3 (0–11)
Activities of daily living* total, n		19.9 (2–67)	13.3 (0–84)
Function* body – and cognitive function/training, n		8.7 (0–48)	6.9 (0–44)
Environment* environmental investigation, technical aids and home modifications, n		4.8 (0–21)	3.4 (0–24)
Family* contact with significant other, n		1.3 (0–17)	1.3 (0–10)
Other* information about home care and rehabilitation, n		0.1 (0–6)	0.2 (0–2)

Note: *Face to face, in group, or by telephone.

Outcomes and estimations at three months

Participants with stroke. The participants' outcomes regarding independence in ADL, perceived participation, life satisfaction, use of home-help service, and satisfaction with training at three months' follow-up are presented in Table III. No significant difference was found between the groups in the primary outcome, participation. There was a difference between the CADL and the UADL groups in the SIS domain "emotion", in favour of the CADL group, but there were no differences in other outcomes or in falls.

Significant others

At three months, 180 significant others were included in the study. Socio-demographic data on the significant others and outcomes are presented in Table IV. There were no significant differences at three months in the CBS, the OGQ, the Lisat-11, or in informal care between the CADL and UADL groups.

Discussion

To our knowledge, this is the first study to evaluate a client-centred ADL intervention in an RCT. At three

months after the start of the interventions, there was no difference between the CADL and UADL groups in the primary outcome, perceived participation, nor were there any differences in the secondary outcomes or in outcomes related to the significant others. However in the SIS domain "emotion" as shown in Table III, there was a difference between the groups in favour of the CADL group. Furthermore, during the three-month period after the start of the intervention, the CADL group received more occupational therapy than the UADL group. This difference might, at least in part, be explained by the fact that 58% of the UADL group compared with 31% in the CADL group received home rehabilitation of shorter duration than inpatient rehabilitation.

Participation and independence in ADL

Participation was the choice of primary outcome as the aim of the CADL was to enable agency and perceived participation in everyday occupations, since people with stroke often perceive restrictions in participation (10). There was no difference at three months between the groups with regard to the primary outcome, perceived participation (see Table III), which is in line with previous studies showing that participation restrictions are common three months

Table II. Baseline, participants with stroke.

Measure, range	Total sample group		Geriatric rehabilitation group		Medical rehabilitation group		Home rehabilitation group	
	CADL (n = 129)	UADL (n = 151)	CADL (n = 68)	UADL (n = 53)	CADL (n = 21)	UADL (n = 11)	CADL (n = 40)	UADL (n = 87)
Age, year mean (SD)	74 (10)	71 (10.8)	77 (7.5)	69 (11.5)	59 (6.0)	56 (10.4)	75 (8.1)	74 (8.6)
Men/women, n (%)	73/56 (57/43)	95/56 (63/37)	31/37	34/19	17/4	6/5	25/15	55/32
Cohabiting, n (%), yes	68 (52.7)	91 (60.3)	33	33	14	8	21	50
Level of education, n (%):								
Elementary school	62 (48.1)	70 (46.4)	34	21	8	3	20	46
High school	32 (24.8)	43 (28.5)	13	16	7	3	12	24
University	35 (27.1)	37 (24.5)	21	15	6	5	8	17
No formal education	0(0)	1 (0.6)	0	1	0	0	0	0
Before stroke:								
TIA, n (%)	15 (11.6)	11 (7.3)	7	4	2	1	6	6
Stroke, n (%)	34 (26.4)	38 (25.2)	17	12	3	1	13	25
Diabetes, n (%)	29 (22.5)	40 (26.5)	19	13	2	1	8	26
Personal & Instrumental-ADL _s (KE) n (%):								
Dependent in P- and I-ADL	16 (12.4)	6 (4)	10	4	0	0	6	2
Independent in P- or I-ADL	34 (26.4)	42 (27.8)	18	14	2	1	14	27
Independent in P- and I-ADL	79 (61.2)	103 (68.2)	40	35	19	10	20	58
After stroke:								
Stroke unit, days mean, (range)	11.2 (3–34)	15.6 (1–60)	7 (3–17)	10.9 (1–60)	19.7 (8–30)	14.5 (7–21)	13.1 (3–34)	18.8 (1–47)
Included days after stroke, mean (range)	24.9 (6–96)	27.7 (3–115)	18.8 (6–77)	20.4 (6–84)	27.8 (8–80)	26.3 (11–67)	34 (7–96)	32.3 (3–115)
Stroke severity, n (%):								
Mild (BI = 50–100)	94 (72.9)	129 (85.4)	45	39	14	11	35	79
Moderate (BI = 15–49)	31 (24)	20 (13.3)	20	13	6	0	5	7
Severe (BI = <15)	4 (3.1)	2 (1.3)	3	1	1	0	0	1
Hemisphere, n (%):								
Left	61 (47.3)	74 (49)	37	21	9	4	15	49

Table II. (Continued).

Measure, range	Total sample group		Geriatric rehabilitation group		Medical rehabilitation group		Home rehabilitation group	
	CADL (n = 129)	UADL (n = 151)	CADL (n = 68)	UADL (n = 53)	CADL (n = 21)	UADL (n = 11)	CADL (n = 40)	UADL (n = 87)
Right	67 (51.9)	74 (49)	30	31	12	7	25	36
Unspecified	1 (0.8)	3 (2)	1	1	0	0	0	2
Hemorrhage	13 (10.1)	19 (12.6)	7	5	4	3	2	11
Infarct	96 (74.4)	110 (72.8)	50	35	16	8	30	67
Unspecified stroke	20 (15.5)	22 (14.6)	11	13	1	0	8	9
Speech production, n (%):								
No aphasia	96 (74.4)	116 (76.8)	56	43	13	10	27	63
Limited vocabulary	25 (19.4)	28 (18.5)	10	7	5	1	10	20
More than yes/no	6 (4.6)	3 (2)	2	1	3	0	1	2
Only yes/no or less	2 (1.6)	4 (2.7)	0	2	0	0	2	2
Mini-Mental State Examination (MIMSE) 0–30, median (inter-quartile range)	26 (23–29)	27 (24–29)	26	26	26	27	27	28
Barthel Index (BI) 0–100, median (range)	65 (5–100)	80 (10–100)	55	65	55	65	82.5	85
Stroke Impact Scale (SIS)								
Recovery 0–100, mean (SD)	31.8 (20.6)	41.7 (24.3)	26.6 (18.2)	38.9 (26.3)	38.3 (23.6)	33.6 (24.1)	37.5 (20.8)	44.4 (23)
Gait, n (%):								
Unable to walk	37 (28.7)	32 (21.2)	27	23	7	2	3	7
Walks with aid and help of another person	35 (27.1)	20 (13.2)	24	10	3	5	8	5
Walks with aid	24 (18.6)	35 (23.2)	9	12	4	2	11	21
Walks 5 m without aid	33 (25.6)	64 (42.4)	8	8	7	2	18	54

Table III. Outcome three months after inclusion, participants with stroke.

Measure, range	Total sample group		Geriatric rehabilitation group		Medical rehabilitation group		Home rehabilitation group	
	CADL (<i>n</i> = 129)	UADL (<i>n</i> = 151)	CADL (<i>n</i> = 68)	UADL (<i>n</i> = 53)	CADL (<i>n</i> = 21)	UADL (<i>n</i> = 11)	CADL (<i>n</i> = 40)	UADL (<i>n</i> = 87)
Barthel Index (BI) 0–100, mean	81.7	77.7	81.6	79.6	80.2	70.2	83.5	83.5
Personal & Instrumental-ADL, (KE) <i>n</i> (%):								
Dependent in P- and I-ADL	72 (55.8)	70 (46.4)	45	31	8	5	19	34
Independent in P- or I-ADL	38 (29.4)	52 (34.4)	19	15	5	3	14	34
Independent in P- and I-ADL	19 (14.7)	29 (19.2)	4	7	8	3	7	19
Stroke Impact Scale (SIS), 0–100, mean:								
Strength	52.7	48.1	54.3	43.3	53.1	45.8	50.8	55.3
Memory, thinking	77.5	75.3	78.9	73.2	79.4	73.4	74.2	79.4
Emotion	69.3	62.5	71.3	65.8	69.1	53.7	67.5	67.9
Communication	77.0	76.2	82.0	77.2	76.7	71.7	72.3	79.6
ADL	65.3	58.8	67.1	59.8	63.3	49.1	65.6	67.6
Mobility	64.2	56.4	68.8	59.2	57.1	42.8	66.8	67.2
Hand function	46.7	42.5	47.3	36.8	46.4	33.5	46.5	57.2
Participation	54.1	52.7	59.5	53.6	50.3	45.1	52.4	59.5
Recovery	51.0	52.3	49.9	51.0	50.9	48.5	52.3	57.4
Occupational Gaps questionnaire (OGQ), 0–28, mean	9.1	10.7	9.3	10.6	9.5	13.4	8.5	8.2
Gait, <i>n</i> (%):								
Unable to walk	18 (14.0)	16 (10.6)	12	10	6	1	0	5
Walks with aid and help of another person	19 (14.7)	10 (6.6)	14	6	0	1	5	3
Walks with aid	31 (24.0)	33 (21.9)	19	14	2	3	10	16
Walks 5 m without aid	61 (47.2)	92 (60.9)	23	23	13	6	25	63
Satisfied with life, (Lisat-11) yes, <i>n</i> (%)	47 (36.4)	56 (37.1)	27	20	8	4	12	32
Home-help service, yes, <i>n</i> (%)	57 (44.2)	60 (39.7)	34	24	6	4	17	32
Satisfied with training, yes, <i>n</i> (%)	94 (72.9)	105 (69.5)	51	32	17	8	26	65
Falls, yes, <i>n</i> (%)	60 (46.5)	73 (48.3)	34	29	12	5	14	39

Table IV. Outcome at three months, significant others.

Measure, range	Total sample group		Geriatric rehabilitation group		Medical rehabilitation group		Home rehabilitation group	
	CADL (n = 87)	UADL (n = 93)	p-value	CADL (n = 33)	UADL (n = 12)	CADL (n = 6)	UADL (n = 30)	UADL (n = 54)
Characteristics:								
Age, year mean (SD)	60 (14.6)	64 (13.1)		65	54	55	63	64
Men/women, n (%)	31/56 (35.6/64.4)	23/70 (24.7/75.3)		6/27	4/8	1/5	8/22	16/38
Cohabiting, n (%)	51/36 (58.6/41.4)	63/30 (67.7/32.3)		23/10	11/1	4/2	19/11	36/18
Outcome at three months:								
Caregiver burden scale (CBS) 22-88, mean	42.5	43.9	0.59	43.0	41.6	47.2	43.0	41.3
Occupational Gaps Questionnaire (OGQ) 0-28, mean	4.9	5.0	0.91	4.8	5.9	6.5	4.6	3.7
Satisfied with life (Lisat-11), yes, n (%)	47 (54.0)	38 (40.9)	0.36	15	5	2	15	21
P-ADL support, yes, n (%)	35 (40.2)	43 (46.2)	0.67	20	4	4	13	19
I-ADL support, yes, n (%)	60 (69.0)	61 (65.6)	0.45	25	7	3	19	33
Other support, yes, n (%)	54 (62.1)	66 (71.0)	0.31	21	9	5	17	40

after stroke (5,7). Since participation is a complex phenomenon (54), there may be several different potential impacts on participation, such as environmental, cultural, and personal factors. Another plausible interpretation of why there was no difference in perceived participation at three months might be that participants in the CADL group had discovered (30) and become more aware of their own difficulties in performing ADL and, for this reason, rated lower in SIS and OGQ. At three months after stroke, lack of awareness of disability is common and known to be related to ADL performance (55) and awareness is a prerequisite for problem solving in valued activities (56). The CADL intervention specifically focused on teaching problem-solving strategies and, thus, awareness of disability may have been facilitated. Furthermore, there was no difference in the secondary outcome, independence in ADL. The ADL-related outcomes, SIS mobility, SIS ADL, and independence in ADL, according to BI, had a slight trend in favour of the CADL. Independence in ADL at three months has been shown to be associated with participation at 12 months after stroke, which may imply that participation might increase in favour of the CADL at 12 months (5). Moreover, the participants who received the CADL specifically learned to solve problems and were supported in applying different strategies to increase participation in valued occupations in their everyday lives and, thus, a higher perceived participation might be expected in the CADL group in long-term follow-ups. The expectations that skills in problem solving may have long-term effects are supported by the findings from studies on early supported hospital discharge (ESD) after stroke, in which the participants who received ESD learned problem-solving strategies (22) and in which receiving ESD was associated with better ADL capacity both at one year (23) and at five years after stroke (24).

Emotion and adverse outcomes

The CADL group scored higher in the SIS domain “emotion” than did the UADL group. One explanation might be that one of the therapeutic strategies applied in the CADL intervention was to take the person’s lived experiences as the point of departure and specifically enable participation in everyday occupations. The focus on activities of the participants’ own choice in planning and goal setting might have contributed to the higher rating in the domain “emotion”, as it has been found that meaningful activities and performing activities one wants to perform have a positive influence on health and well-being (20,57). To enable engagement in activities by learning how to use and implement a problem-solving strategy in everyday occupations might have had a

positive influence on emotion and experience of agency. This difference between the groups in the SIS domain “emotion” is important, because emotional changes and depressive symptoms can have a negative impact on the outcomes of rehabilitation. Cardol and colleagues have found that emotional distress was the most important factor explaining restrictions in participation (58).

It was unexpected and it is hard to find an explanation for why, at three-month follow-up, only half as many participants were deceased in the CADL group compared with the UADL group, considering that the CADL group was the older group. There were no differences between the groups in adverse outcomes, such as self-reported falls.

Life satisfaction and caregiver burden

Neither the participants with stroke who received the CADL nor their significant others perceived a higher global life satisfaction at three-month follow-up than those who received UADL and there were no differences between the groups regarding caregiver burden or in proportion of significant others who provided informal care. The hypothesized difference in life satisfaction, caregiver burden, and informal care between significant others in the CADL group and the UADL group was based on the assumption that there would be a difference in dependence in ADL at three months between the participants with stroke in the CADL and the UADL group. This assumption was based on empirical findings that there is an impact on life satisfaction both for the persons with stroke and their significant others, linked to the level of dependency in ADL (59) and caregiver burden (12). Hence, in the absence of a difference in dependence in ADL, the major rationale for a difference in life satisfaction, caregiver burden or in proportion involved in informal care between the groups was no longer present.

Several authors have stressed the importance of involving the clients more in their own rehabilitation (60) and, as client-centred care can be further developed and applied in Sweden, there is an urgent need for improvement (34). One way of understanding the differences between groups in the SIS domain “emotion” and the amount of OT received might be that a client-centred approach that is developed directly from the person’s lived experiences is more time-consuming but that this is a better support for the person’s emotional well-being. Long-term follow-ups are thus imperative as this initial increase in time required should be understood in relation to the plausible advantages envisioned in the long run with regard to the health and well-being of the person with stroke and the significant other and their need for

and use of health services. Second, the need for clarification and a common understanding of the concept of client-centredness, its aims, and consequences is emphasized. Otherwise, it will continue to be mere rhetoric (61).

Methodological considerations

The RCT design was selected to provide a scientifically rigorous evaluation of this new client-centred ADL intervention. One strength of the study is that the participating sites were randomized and stratified by type of rehabilitation unit across three counties in Sweden, representing both urban and rural areas, as the context in which a study is performed may affect the outcome (62). Furthermore, the randomization of rehabilitation sites instead of participants was chosen in order to maintain contrast and to reduce the risk of contamination between the intervention and the control condition, a risk identified in the preceding pilot study (31). The type of rehabilitation was not equally distributed between the CADL and the UADL groups but that was controlled for in the analyses. Also, and in line with the CONSORT (1), both the independent data collectors and the statistician were blinded to the group association of the rehabilitation units and the participants, and intention-to-treat analyses were applied. Moreover, all OTs delivering interventions in the course of the study were contacted regularly, which, in the case of the CADL group, aimed to support fidelity to the CADL intervention that they had been taught in a one-week workshop. The possibility that the UADL intervention included client-centred approaches cannot, however, be ruled out since the client-centred perspective has been much discussed among OTs in the past decade (61). Neither can the possibility be ignored that the difference between the two interventions might have been too small to have a significant effect on the outcomes.

There are several difficulties involved in conducting RCTs of complex interventions, which are subject to more variation than a drug (62), in clinical contexts where other differences between the groups, apart from the interventions under study, occur. Consequently, information on the content of the OT sessions, both in the CADL and in the UADL, was collected and presented in order to describe the variations within the interventions as recommended for studies of complex interventions (1). The differences revealed in content are in line with intended differences between the CADL and UADL, indicating that the CADL was conducted as planned. The CADL group had more OT contacts and the possibility that the larger number of OT contacts contributed to the results cannot be ruled out. The CADL group was older and had lower ADL capacity at

inclusion (shown in Table II), which makes it probable that the CADL group required more OT contacts. However, a client-centred approach is likely to require more time, regardless, if it is to take its point of departure in the life world of the person with stroke. A limitation of the study is the lack of information regarding interventions delivered by other professions in parallel with the CADL or the UADL. An underlying assumption in an RCT is that variations are random and similar in both groups but there is no information available to support this assumption. At inclusion, there were some imbalances between the groups that are likely to have an impact on the outcome, e.g. age, sex, and stroke severity and, consequently, these were included as confounders in all statistical analyses. Nevertheless, the variation in time between stroke incidence and inclusion in the study might be considered a limitation but, as this variation was similar in both groups, it is likely that there was no difference in impact on natural recovery between the groups.

Our aim was that the results of the study would be of use clinically to guide OTs and other professionals in the rehabilitation team on how to bring about a client-centred ADL intervention in stroke rehabilitation. Consequently we chose a pragmatic approach with wide inclusion criteria and 16 different rehabilitation units. However, as it was the OTs at the various rehabilitation units who applied the inclusion criteria and, thereafter, suggested suitable participants to the researchers, the possibility that additional implicit inclusion criteria were applied cannot be ruled out. Participants with speech and language difficulties and severe strokes were, however, included in both the CADL and the UADL group but it is likely that there may have been more people with stroke who met the inclusion criteria than those approached and included in the study.

We conclude that the CADL had beneficial effects on self-rated emotional well-being three months after the intervention started but that there were no other differences in effects for people with stroke or their significant others compared with UADL. Longer follow-ups are, thus, required to monitor plausible advantages in outcomes of a client-centred approach. Furthermore, it is conceivable that a client-centred approach that aims to establish a relationship based on the person's lived experiences as the point of departure for rehabilitation will require more time than the usual rehabilitation procedure, regardless of rehabilitation context.

Other information

The Regional Ethical Review Board in Stockholm approved the study. Registration Clinical Trials gov. identifier: NCT01417585.

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