Thematic panel 8. Reablement as a strategy to regain independence: its challenges and impacts.

A multicenter investigation of reablement in Norway: a clinical controlled trial

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Abstract

Background: Reablement has become an emerging approach in the rehabilitation services for community-dwelling older adults experiencing functional decline. However, the results are inconsistent and relatively scarce when it comes to the health effects of reablement.

Objective: To investigate the effects of reablement in home-dwelling adults on activity performance and satisfaction with activity performance, physical function, health-related quality of life (HQoL), coping as a sense of coherence and positive mental health.

Design: A large multi-centre, clinical controlled trial involving 43 Norwegian municipalities in Norway, with assessments made after 10 weeks, 6 and 12 months.

Sample: A total of 712 home-living persons received a four to 10 weeks reablement program and 121 persons received treatment as usual.

Methods: Primary outcomes were the Canadian Occupational Performance Measure (COPM) that was used to measure performance of daily activities (COPM-P) and satisfaction with that performance (COPM-S). Secondary outcomes included physical function measured with The Short Physical Performance Measure Battery (SPPB) including total score (0-12) and the subscales (0-4) balance, walking and sit-to-stand. HQoLwas measured with The European Quality of Life Scale (EQ-5D-5L) including the subscales (1-5) mobility, personal care, usual activities, pain/discomfort, anxiety/depression and visual analog scale (VAS, 0-100). Coping as a sense of coherence was measured with The Sense of Coherence Questionnaire (SOC -13, 13-91) and positive mental health measured with the Mental Health Continuum-Short Form (MHC-SF, 0-70).

Overall treatment effects were estimated with Mixed models repeated measures analyses.

Results: Significant treatment effects in favor of the rehabilitation group were found in COPM-P and COPM-S scores at 10 weeks (mean differences between groups 1.46, 95 % confidence interval (CI): 0.98, 1.94 and 1.31, CI: 0.82, 1.81, respectively) and 6 months follow up (mean differences between groups, 1.23, CI: 0.65, 1.81 and 1.17, CI: 0.58, 1.76, respectively). However, at 12 months the differences between the treatment and control

group were no longer significant, (mean differences between groups, for COPM-P 0.76, CI:-0.07,1.58 and for COPM-S 0.59, CI:-0.27,1.45, respectively).

There was a significant treatment effect in favor of the rehabilitation group in the subscales balance (0.33, CI: 0.08,0.58) and walking (0.34, CI: 0.08,0.60) after six months and in the total SPPB score (0.93 CI: 0.15,1.71) and in the subscale sit-to-stand (0.47, CI: 0.10,0.83) after 12 months.

In EQ-5D-5L significant treatment effect in favor of the rehabilitation group were found in the subscales mobility (-0.34,CI:-0.54, -0.14), personal care (-0,19, CI: -0.37,-0.02) and usual activities(-0.23, CI:-0,45,-0,01) and health today (7,04, CI: 2,37,11.70) after six months. There were no significant differences in the pain/discomfort dimension (-0.11, -0.32, 0.10) and anxiety/depression dimension (-0.04, CI:-0.21,0.12) after six months. There was no significant differences in EQ-5D-5L after 12 months.

In SOC and MHC-SF there were no significant differences at any measurement.

Conclusion:

In summary, the findings of the present study show significant effects in favor of the reablement on different outcomes after six months. After 12 months the effects decreases, indicating a need for follow-up interventions in the reablement group. The present study makes an important contribution to our knowledge of rehabilitation approaches for community-dwelling adults.

Introduction

Globally, the share of older persons in the total population is increasing (World Population Ageing, 2015). Combined with an expected shortage of health care personnel, the aging population will present a challenge to the sustainability of the health care system in years to come (OECD, 2013). Hence, several high-income countries have promoted a shift from residential care to home-based care, believing it to be a more effective and financially sustainable approach (Rostgaard et al 2011). Further, the increasing proportion of older people prefer to age in place as well as to be active in everyday life and in the society. This require more home-based rehabilitation. Therefore, reablement, or restorative care as it is also called, has become an emerging approach in the rehabilitation services for community-dwelling older adults experiencing functional decline (Aspinal et al, 2016).

Reablement as an intervention is often insufficiently described and are carried out in different ways (Pettersson and Iwarsson, 2017). In a newer Cochrane review reablement is defined as an intervention that is person-centred and goal-directed, time-limited and intensive. It is provided from a multidisciplinary team in the home setting or in the local community and

focus on maximising independence. Participants must have an identified need for formal care and support, or be at risk of functional decline (Cochrane et al, 2016).

The effect of reablement in terms of improvement of participants' independence in activities of daily living (ADL) have been summarized in five systematic reviews (Cochrane et al, 2016, Whitehead et al, 2015, Tessler et al, 2016, Sims-Gould et al, 2017, Pettersson and Iwarsson, 2017). The results of the reviews are inconsistent in terms of whether reablement results in improved independence in ADL or not. Three reviews found limited improvement in favour of reablement (Cochrane et al, 2016, Whitehead et al, 2015, Sims-Gould et al, 2017) whereas two reviews are inconclusive (Tessler et al, 2016, Pettersson and Iwarsson, 2017). One systematic review and five studies have explored whether reablement improves physical functioning. While the systematic review (Pettersson and Iwarsson, 2017) is inconclusive, three studies are in favour of reablement (Parsons et al, 2013, Tinetti et al, 2002, Lewin et al, 2010), whereas two studies are not (Burton et al, 2013, Lewin et al, 2013). As such, firm conclusions whether reablement improves physical function, can hardly be drawn. Three systematic review and two studies have examined whether reablement improves health-related quality of life (Tessler et al, 2016, Cochrane et al, 2016, Pettersson and Iwarsson, 2017, Parsons et al, 2012, Glendenning et al, 2010). Although there is a tendency in favour of reablement, there is inconsistency whether reablement leads to better health-related quality of life.

In summary, the results are inconsistent and relatively scarce when it comes to the health effects of reablement.

Hence, the main purpose of this study was to investigate the effects of reablement in homedwelling adults on activity performance and satisfaction with activity performance, physical function, health-related quality of life, coping as a sense of coherence and positive mental health.

Method

This was a large multi-centre, clinical controlled trial involving 43 Norwegian municipalities, in which the intervention group received reablement and the control group received standard care. The study was commissioned by the Norwegian Directorate of health. The participants were assessed at baseline, and again at 10 weeks`, 6 months` and 12 months` follow-up. People were eligible if they were home-dwelling, over 18 years of age, understood Norwegian and had experienced functional decline. People were excluded if they were in need of institution-based

rehabilitation or nursing home placement, or if they were terminally ill or cognitively reduced. The study protocol has been published previously (Langeland et.al, 2015). The study was registered in Clinical Trials.gov (October 24, 2014).

Interventions

Reablement

In the present study reablement is defined as an intensive, time-limited, goal-directed interdisciplinary intervention provided in the person's home or local community. This definition is compatible with the definition given in Cochrane review (Cochrane et al, 2016). In general, the intervention lasts for a period of 4-10 weeks. The main focus is to establish a dialog to identify activities that the individual perceives as meaningful to work on or to improve. The intervention is targeted towards achieving these activity goals. Thus, the person -specific Canadian Occupational Performance Measure (COPM) was used as part of the baseline assessments to provide directions for the modeling of the reablement intervention. During the COPM assessment, the participant defined up to five activity goals that were essential to her or him. Based on these goals, a rehabilitation plan was developed to promote a match between the activities and goals identified by participants, and professional initiatives. Intensive attention was given to encourage participation and stimulate daily training for the participants, including performing their daily tasks themselves. Since individual tailoring is a major principle of reablement, the content of the intervention will vary among participants, although the basic features are the same. Details concerning the content of the intervention can be found in the protocol (Langeland et al, 2015).

The control intervention

The control group received standard treatment. In contrast to reablement, the standard treatment was not time-limited. Standard care often comprised compensating help and the content of the compensating help was delivered according to the applications made by the participants. This involved personal or practical assistance, meals on wheels, safety alarm, or assistive technology. However, it involved also rehabilitation efforts to some degree by health professionals such as occupational therapists and physiotherapists. This implies that the standard treatment varied among participants and municipalities.

Training of the intervention providers and contact persons in each municipality

We arranged a two-day course where representatives from all 43 municipalities received training in performing the data collection procedures, as well as designing and delivering the intervention. On the first day, an expert on COPM gave lectures and instructions, including practical exercises. On the second day, the principal investigator and project coworker presented the data collection procedures and the required key elements of the reablement intervention. Each municipality had a contact person who was responsible for the different procedures employed in the project, including data collection instruments. They were encouraged to use videos to demonstrate how to perform the COPM interviews and the physical function test. It was important to ensure compliance to the intervention and the data collection period, and the contact persons and health care providers were encouraged to contact the principal investigator if they needed to discuss different issues related to the project.

Data collection

Sociodemographic variables

We collected sociodemographic characteristics of the participants such as age, sex, marital status, education and whether they lived alone or not. In addition the participants reported their major health challenge and other health challenges. Motivation for rehabilitation was scored on a 1-10 point scale, where 10 was best. Given the holistic approach in reablement we included five instruments that had the potential to capture various effects of reablement.

Primary outcomes

The Canadian Occupational Performance Measure (COPM) was used to measure performance of daily activities and satisfaction with that performance. This instrument measures a person's self-perception of activity performance within three occupational performance areas; self-care, productivity and leisure (Law et al, 2008). During a semi-structured interview, participants describe which activities they experience as important, but difficult to perform. The importance of each activity is rated on a 1-10 point scale (10 = very important). Next, the participant is asked to prioritize maximum five of the most important activities and thereafter rate activity performance (COPM-P) and satisfaction with activity performance (COPM-S) of

each of these activities on a scale from 1-10 (higher score reflects better performance and higher satisfaction). Sum scores for the COPM-P and COPM-S, respectively, were calculated by adding the performance or satisfaction scores and thereafter divide by the number of prioritized activities. The minimal important change is found to be 3.0 and 3.2 points for COPM-P and COPM-S respectively (Tuntland et al, 2016). The psychometric properties of the COPM are found to be adequate in a home-dwelling, older population (Tuntland et al, 2016).

Secondary outcomes

The Short Physical Performance Measure Battery (SPPB) was applied to measure physical function. The SPPB aims to identify people at risk of functional decline, and it is a screening test for mobility (Guralnik et.al, 1994) The SPPB comprises: 1) standing balance including side-by-side standing, and semi-tandem and tandem standing; 2) a walking test for four meters at regular pace; and 3) standing up and sitting down rapidly five times. For each item, the time required is recorded and converted into points (0–4), thereby giving a total score of 0–12 points. Based on the four-meter walking test, the preferred walking speed was calculated. A walking speed >1.0 m/s is perceived as normal, a speed between 0.6 and 1.0 is perceived as initial disability, and a walking speed <0.6 is perceived as reflecting frailty (Studenski et al, 2003). In a systematic review it was revealed that the SPPB has good validity, reliability, and responsiveness (Freiberger et al., 2012).

The European Quality of Life Scale (EQ-5D-5L) was used to measure health-related quality of life. EQ-5D comprises a questionnaire and a visual analog scale (VAS). The EQ-5D questionnaire has five domains (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) (The EuroQol Group, 1990). The responses are scored on a five-point ordinal scale from 1 to 5, where a score of 1 is best. Hence, a decrease in score represents an improvement. The health today VAS scale is an indication of how individuals value their own health on a scale of 0–100, with 100 being excellent health. A structured review of the psychometric properties of the EQ-5D concluded that there is good evidence for reliability, validity and responsiveness among older adults (Hatwood et al, 2005).

The Sense of Coherence Questionnaire (SOC -13) was used to measure coping related to experiences of coherence in life. SOC-13 was developed by Antonovsky (1987). SOC-13 is self-reported and it comprises 13 items related to comprehensibility (five items), manageability (four items), and meaning (four items). The total score ranges from 13 to 91,

where higher scores indicate a stronger sense of coherence. A systematic review concluded that the SOC scale appears to be a reliable, valid, and cross-culturally applicable instrument for measuring how people manage stress and stay well (Eriksson and Lindström 2005).

The Mental Health Continuum-Short Form (MHC-SF) was applied to measure positive mental health. The MHC-SF is designed to measure three dimensions of the positive mental health concept: emotional well-being, psychological well-being, and social well-being (Keyes, 2002, 2005). The MHC-SF comprises 14 items and the possible score range is 0–70. Each item is scored by rating the frequency of different feelings during the past month on a six-point scale, ranging from never (0) to every day (5). Higher scores indicate higher levels of positive mental health (Keyes, 2002, 2005). The MHC-SF has been translated into Norwegian (Langeland et al, 2013). In a study with a large sample of people aged 18-87 years, validity and reliability have been shown to be good (Lamers et al, 2011).

Statistical analysis

We calculated the sample sized based on an earlier study performed on older adults, in which the standard deviation for the primary outcome was shown to be 1.4 for COPM performance and 1.6 for COPM satisfaction (Richardson et.al 2000). Since the current trial is a multicenter study with 43 participating municipalities, we expected that the variation in the COPM scores would be larger, and thus we employed a conservative estimate of 2.5 for the standard deviation. Furthermore, the allocation of participants to the intervention group or control group was not randomized, and we estimated that the number of participants in the intervention group probably would be three to four times that in the control group. We aimed to detect a change of one point as statistically significant at a two-sided 5% level and with a power of 80%. Based on these estimates, sample size calculations indicated that we needed to include 70 participants in the control group and 260 in the intervention group. Thus, considering the possibility of a relatively high dropout rate (up to 35%) due to frail participants, we calculated a priori that a minimum of 107 and 400 participants were needed in the control and intervention groups, respectively.

Descriptive statistics of the sample's sociodemographic and clinical characteristics were performed. Mean (standard deviation) and median values (interquartile range), or numbers and percentages are reported. The analyses were based on the intention-to treat principle.

Differences at baseline between participants in the two groups were analyzed by independent samples t-tests for means and x^2 for proportions. P-values are reported two-sided and significant at $P \le 0.05$.

The data are suitable for multilevel or hierarchical modeling. Individuals are nested within municipalities and municipalities will be treated as fixed effects when mixed-effects models are applied (Hox, 2002). To evaluate whether the effect of the intervention varies according to sociodemographic characteristics and home municipality, linear mixed-effects models are used. Given the multilevel structure of the data (individuals over time within municipalities), we will control for stable differences between municipalities using a so-called fixed-effects model.

The statistical analyses were performed using Stata version 14.2 (StataCorp, 4905 Lakeway Drive College Station, Texas, USA)

Ethical approval

The trial was approved by The Regional Committee for Medical and Health Research Ethics for Western Norway (REK West, 2014/57-1). Participants have been coded and the analysis have been performed anonymously. The procedures were conducted in accordance with the Declaration of Helsinki (1975), as revised in 2013 (World medical Association, 2013). Each participant has signed a declaration of voluntary participation with information about the study purposes and consequences, emphasizing the right to withdraw from the study.

Results

Participant flow and study sample

Approximately 17% of the Norwegian population was living in the municipalities included in this study. Both rural and urban municipalities of various sizes, stretching out from the north to the south of Norway, were included.

A total of 833 participants were included in the study divided into 712 in the intervention group and 121 in the control group. When continuous recruitment of participants was completed in June 2015 and all data collection ended in December 2015, there were 268 (233 in the intervention group and 35 in the control group) of totally 833 participants at baseline

(720 in the intervention group and 129 in the control group) who did not reached 12 month's follow up. These are categorized as not reached in the flow chart (Figure 1). At 10 weeks the drop-out rate was 13.6% and at 6 months follow up the drop-out rate was 20%. Totally 217 participants dropped out of the study at 12 months, giving a dropout rate of 26%. The most frequent reasons for dropping out was that their health was poor, they no longer could bear to participate, they got temporary or permanent institution placement or they died. Dropout analyses revealed that it was no difference on baseline scores for respectively COPM performance and satisfaction between those who dropped out and those who responded at 10 weeks follow up (p=0.65, and p=0.95, respectively).

Table 1 is displaying baseline participant's characteristics in total and for each group. The baseline characteristics of the participants are not significantly different between the control and reablement group, except for the motivation variables were the participants in rehabilitation group are slightly more motivated than the control group participants are. The participants were on average 78 years old, (ranging from 19 to 97), 2/3 were women, roughly, 1/5 had higher education and 2/3 were living alone. They had a range of health challenges, with fractures (20.3 %), dizziness (15.1%), pain (9.9 %), stroke (7.5 %) and heart disease (5.9%) as being the most common. Most of the participants reported in addition two other health challenges.

	All participants (825-830)	Rehabilitation group (702-710)	Control group (119- 120)	P- values ª
Age, years, mean (SD)	78.4 (10.9)	78.2(11.2)	79.5(9.3)	0.22
Female, n (%)	575 (69.3)	488 (68.7)	87 (72.5)	0.41
Higher education, n (%)	167 (20.3)	140 (19.9)	27 (22.5)	0.52
Living alone	596 (71.6)	502 (70.7)	94 (78.3)	0.38
Motivation, 1=Not motivated at all –	8.1 (2.1)	8.2 (2.0)	(7.4 (2.6)	< 0.00
10 = Very motivated, mean (SD)				

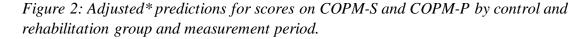
Table 1: Baseline characteristics of participants allocated to reablement (rehabilitation group) or treatment as usual (control group)

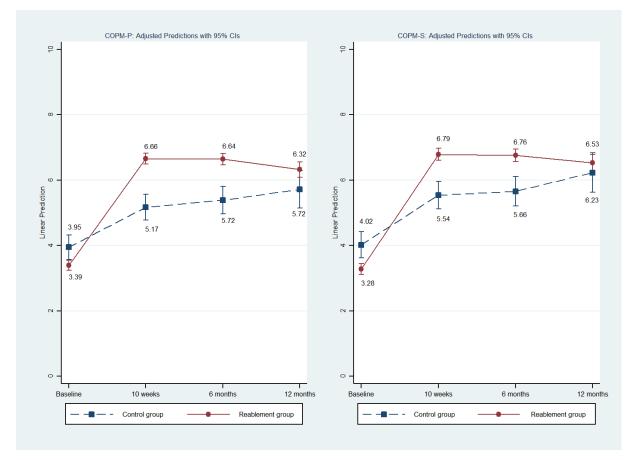
a Difference between groups (independent samples t-test for means, and χ^2 for proportions)

Effects for participants

Performance of and satisfaction with performance in daily activities (COPM)

We start with showing the development of mean scores of COPM-S and COPM-P. Figure 2 reports adjusted predictions for scores on COPM-S and COPM-P by control and intervention group for the different measurement periods. The figure shows that the intervention group had a lower score at baseline compared to the control group both for COPM-S and COPM-P, p = <.0.001, see table 2. After 10 weeks and 6 months, we see an increase for the intervention group that surpasses the mean score for control group. At 12 months, the differences in scores between control and intervention group are decreasing and no longer significant for COPM-S.





*Adjusted for baseline score.

In the remaining, we present results from mixed-effects models. In these analysis the difference between the scores at respectively 10 weeks, 6 months and 12 months follow –ups and baseline scores were used as dependent variables and individuals nested within municipalities as the hierarchical structure. We group the participants within municipalities they reside in to assess the effect of municipal belonging. Furthermore, for each dependent variable we adjust for age, gender, education and motivation. In addition, baseline scores for

the respective dependent variables were included as independent variable. This was done since baseline score may predict change of score.

Primary outcomes

Performance of and satisfaction with performance in daily activities (COPM)

There was a significant treatment effect in favor of the rehabilitation group in both COPM-P and COPM-S scores at 10 weeks (mean differences between groups 1.46, confidence interval (CI): 0.98, 1.94 and 1.31, CI: 0.82, 1.81, respectively) and 6 months follow up (mean differences between groups, 1.23, CI:0.65,1.81 and 1.17, CI:0.58,1.76, respectively). However, at 12 months the differences between the treatment and control group are no longer significant, indeed border significant (p=0.07) for COPM-P (mean differences between groups, 0.76, CI:-0.07,1.58 and 0.59, CI:-0.27,1.45, respectively) (see Table 2). The results indicate that females are significantly more likely to improve at all follow-ups except for COPM-S at 6 months were the difference between male and female is not significant (p=< 0.10). See table 3. Further, those who are most motivated at baseline are scoring better on COPM at all follow-ups. (COPM-P and COPM-S p=<0.05) The education variable is not significant at any point. For the age variable, the significant findings are at baseline and 10 weeks for COPM-S were older-aged participants are more satisfied with performance (Baseline p<0.001, 10 weeks p<0.05). See more details in table 3.

Furthermore, the results demonstrate that those who score lower on COPM at baseline are improving their COPM score on all measurements point to a greater degree than those scoring higher at baseline (COPM-P 10 weeks p<0.001, 6 months and 12 months p<0.05; COPM-S 10 weeks and 6 months p<0.001, 12 months p<0.01). See table 3.

Table 2: Baseline values and mean changes from baseline to follow-ups (95 % confidence
interval (CI)) score for treatments effects with p-values) estimated with mixed models linear
repeated measures analysis ^a

	Reablement group, Mean (95% Cl)	Control group, Mean (95 % CI)	Treatment effect (95 % CI)	<i>p</i> -value
Activity perfo (COPM-P) (1-1				
Baseline	3.42 (3.22,3.63)	3.91 (3.53, 4.28)		< 0.001
10 weeks	3.17 (2.96, 3.38)	1.71 (1.26, 2.16)	1.46 (0.98, 1.94)	< 0.001
6 months	3.19 (2.93, 3.45)	1.96 (1.42, 2.50)	1.23 (0.65, 1.81)	<0.001

12 months	2.78 (2.41, 3.14)	2.02 (1.26, 2.77)	0.76 (-0.07, 1.58)	0.07
	vith performance			
(COPM-S) (1-1	•	4 04 (2 60 4 42)		-0.001
Baseline	3.27 (3.05, 3.48)	4.01 (3.60, 4.42)	1 21 (0 02 1 01)	<0.001
10 weeks	3.40 (3.20, 3.61)	2.09 (1.64, 2.55)	1.31 (0.82, 1.81)	<0.001
6 months	3.42 (3.17, 3.67)	2.25 (1.70, 2.80)	1.17 (0.58, 1.76)	< 0.001
12 months	3.17 (2.78, 3.55)	2.57 (1.79, 3.36)	0.59 (-0.27, 1.45)	0.18
Secondary ou	tcomes			
Mobility (EQ-	•			
(1-5, low=bes	•			
Baseline	2.85 (2.76, 2.94)	2.64 (2.44, 2.83)		0.06
10 weeks	-0.60 (-0.68, -0.53)	-0.15 (-0.32, 0.03)	-0.46 (-0.65, -0.27)	0.00
6 months	-0.56 (-0.64, -0.49)	-0.22 (-0.41, -0.04)	-0.34 (-0.54, -0.14)	0.00
12 months	-0.48 (-0.60, -0.36)	-0.29 (-0.56, -0.02)	-0.19 (-0.48, 0.11)	0.21
Personal care	(EQ-5D)			
(1-5, low=bes	st)			
Baseline	2.04 (1.93, 2.15)	1.81 (1.60, 2.03)		0.27
10 weeks	-0.47 (-0.53, -0.41)	-0.15 (-0.29, -0.02)	-0.32 (-0.46, -0.17)	0.00
6 months	-0.40 (-0.47, -0.33)	-0.21 (-0.37, -0.05)	-0.19 (-0.37, -0.02)	0.03
12 months	-0.42 (-0.53, -0.32)	-0.20 (-0.42, 0.02)	-0.22 (-0.47, 0.02)	0.07
Usual activitie	es (EQ-5D) (1-5, low=best)			
Baseline	2.86 (2.76. 2.97)	2.76 (2.54, 2.97)		0.33
10 weeks	-0.54 (-0.70, -0.39)	-0.31 (-0.68, 0.05)	-0.23 (-0.63, 0.17)	0.26
6 months	-0.62 (-0.71, -0.53)	-0.39 (-0.59, -0.18)	-0.23 (-0.45, -0.01)	0.04
12 months	-0.64 (-0.77, -0.51)	-0.40 (-0.68, -0.12)	-0.24 (-0.55, 0.06)	0.12
Pain/discomf (1-5, low=bes				
Baseline	2.65 (2.54. 2.77)	2.64 (2.41, 2.86)		0.94
10 weeks	-0.20 (-0.28, -0.13)	-0.13 (-0.31, 0.05)	-0.07 (-0.27, 0.12)	0.44
6 months	-0.23 (-0.31, -0.15)	-0.12 (-0.31. 0.07)	-0.11 (-0.32, 0.10)	0.31
12 months	-0.23 (-0.35, -0.11)	-0.21 (-0.47, 0.05)	-0.02 (-0.30, 0.26)	0.89
Anxiety/depr	ession (EQ-5D) ^{†)}			
Baseline	1.86 (1.77. 1.94)	1.65 (1.47, 1.84)		0.10
10 weeks	-0.13 (-0.19, -0.06)	-0.24 (-0.38, -0.10)	0.11 (-0.04, 0.27)	0.16
6 months	-0.17 (-0.23, -0.10)	-0.12 (-0.28, 0.03)	-0.04 (-0.21, 0.12)	0.60
12 months	-0.20 (-0.28, -0.11)	-0.22 (-0.41, -0.02)	0.02 (-0.19, 0.23)	0.84
Health today	(FO-5D)			
(0-100, high =				
Baseline	49.65 (47.94, 51.36)	53.44 (49.69, 57.20)		0.06
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10 weeks	8.09 (6.66. 9.51)	2.85 (-0.47, 6.17)	5.24 (1.61, 8.86)	0.01
6 months	9.04 (7.01, 11.08)	2.01 (-2.32, 6.33)	7.04 (2.37, 11.70)	0.00
12 months	7.53 (5.33, 9.73)	5.44 (0.40, 10.47)	2.10 (-3.42, 7.61)	0.46
	physical function , high = best)			
Baseline	4.86 (4.53, 5.19)	5.75 (5.12, 6.38)		0.18
10 weeks	1.71 (1.47, 1.95)	0.45 (-0.05, 0.94)	1.26 (0.73, 1.80)	0.00
6 months	1.67 (1.43, 1.91)	0.51 (0.00, 1.03)	1.16 (0.60, 1.71)	0.00
12 months	1.46 (1.12, 1.80)	0.53 (-0.18, 1.24)	0.93 (0.15, 1.71)	0.02
Balance - su (0-4, high =	u m score (SPPB) best)			
Baseline	2.25 (2.12, 2.38)	2.44 (2.16, 2.72)		0.59
10 weeks	0.56 (0.45, 0.66)	0.15 (-0.09,0.39)	0.31 (0.06, 0.57)	0.02
6 months	0.54 (0.42, 0.67)	0.09 (-0.14, 0.32)	0.33 (0.08, 0.58)	0.01
12 months	0.47 (0.34, 0.61)	0.14 (-0.15, 0.43)	0.31 (-0.07, 0.68)	0.11
	- ()			
Walking - su (0-4, high = 1	u m score (SPPB) best)			
Baseline	1.81 (1.68, 1.95)	2.15 (1.90, 2.41)		0.17
10 weeks	0.56 (0.45, 0.66)	0.20 (-0.01, 0.41)	0.35 (0.13, 0.58)	0.00
6 Months	0.54 (0.42, 0.67)	0.20 (-0.04,0.45)	0.34 (0.08, 0.60)	0.01
12 Months	0.47 (0.34, 0.61)	0.34 (0.06, 0.63)	0.13 (-0.18, 0.44)	0.42
Sit-to-stand (0-4, high = 1	l - sum score (SPPB) hest)			
Baseline	0.80 (0.69, 0.91)	1.11 (0.89, 1.33)		0.10
10 weeks	0.72 (0.64, 0.81)	0.15 (-0.04, 0.35)	0.57 (0.35, 0.79)	0.00
6 Months	0.71 (0.62, 0.81)	0.27 (0.05, 0.50)	0.44 (0.20, 0.68)	0.00
12 Months	0.69 (0.53, 0.84)	0.22 (-0.11, 0.55)	0.47 (0.10, 0.83)	0.01
	(/	- (- , ,	- (,,	
Sense of col (13-91, high	herence (SOC-13) ==best)			
Baseline	68.44 (67.35, 69.54)	69.68 (67.40, 71.97)		0.28
10 weeks	0.19 (-0.90, 1.27)	-1.29 (-3.47, 0.89)	1.46 (-0.88, 3.81)	0.22
6 months	0.21 (-1.20, 1.61)	-2.36 (-5.08, 0.36)	2.56 (-0.32, 5.45)	0.08
12 months	0.57 (-1.16, 2.31)	0.06 (-3.31, 3.43)	0.51 (-3.17, 4.19)	0.79
MHC-SF	(0-70, high=best)			
Baseline	43.38 (41.92, 44.84)	44.06 (41.15, 46.98)		0.27
10 weeks	4.90 (3.95, 5.85)	2.83 (0.62, 5.04)	2.07 (-0.35, 4.49)	0.09
6 months	1.79 (0.65, 2.93)	-0.40(-2.83, 2.03)	2.19 (-0.43, 4.81)	0.10
12 months	2.72 (1.05, 4.39)	0.16 (-3.23, 3.55)	2.56 (-1.17, 6.28)	0.18
^a Adjustment	for the baseline mean valu	e of the variable, age, edu	cation. gender. motivation	

 $^{\rm a}\mbox{Adjustment}$ for the baseline mean value of the variable, age, education, gender, motivation and municipality

Table 3: here.

Secondary outcomes

Physical function (SPPB)

There was a significant treatment effect in favor of the rehabilitation group in the total physical function score and in the subscale sit-to-stand after 12 months. In the subscales balance and walking there were significant differences after six months but no significant differences after 12 months (Table 2).

The results show in general both for total score and for subscales that the younger participants are scoring better at baseline and improve more. Female improved more than male participants at 6 months (p<0.05) for total score and at walking at 6 months (p<0.05) and sit-to-stand at 12 months (p<0.05). Those with higher education had a better total score at baseline (p<0.05) and more improvement after10 weeks, six and 12 months (p<0.01 at all three follow-ups) at total score and all the subscales.

In terms of education the participants with higher education scored better at baseline (p<0.05) and improved more in total score (<0.01), and at balance (p<0.05) after 12 months. Participants with higher education improved more after 6 and 12 months for walking (p<0.01 and p<0.05 respectively). For Sit-to-stand the participants with higher education had better scores at baseline (p<0.05) and better improvement after 12 months (p<0.01).

Motivation was an important explaining factor indicating the better motivation at baseline, the more improvement at 10 weeks (p<0.001) and 6 months (p<0.01) for total score. The variable motivation also yielded significant and positive results for the subscales at various measurements points (Balance: 10 weeks p<0.001, 6 months p<0.05; Walking 10 weeks six and 12 months p<0.05, 6 months p<0.01; Sit-to-stand 10 weeks p<0.01).

Using the baseline scores for SPPB (total score and subscales) as independent variables yields the same results as for COPM: those who have a lower starting point improve more than participants who score better at baseline, the latter in fact showing a negative trend on all follow-ups (p<0.001 at all follow-up measures).

Health-related quality of life (EQ-5D)

There was a significant treatment effect in favor of the rehabilitation group in health related quality of life in the mobility, personal care and usual activities and health today after six months, but no significant differences in the pain/discomfort dimension and anxiety/depression dimension. For all these three variables, there are no significant differences after 12 months (Table 2).

Older participants were more inclined to report more difficulties with Mobility at baseline (p<0.001), 10 weeks (p<0.01), 12 months (p<0.05), usual activities: at baseline (p<0.01), pain/discomfort at baseline, 6 months and 12 months (p<0.01), respectively), 10 weeks (p<0.05), and anxiety/depression at baseline (p<0.01) and 10 weeks (p<0.05). In the subscale personal care were there was no significant results. The overall "Health today" scale shows that the older participants were more inclined to report higher score) than the younger participants at baseline (p<0.01) and 10 weeks (p<0.05).

Female participants improved more in mobility at 6 and 12 months (p<0.05,) and personal care and usual activities after 12 months (p<0.05.) For Pain/Discomfort and Anxiety/Depression female were more likely to report higher scores (negative) at baseline (p<0.01) but this is not significant for the three other measurement points. For health today women improve significantly more at 12 months (p<0.05).

The more motivated participants were the more they were likely to report better mobility at 10 weeks (p<0.01); personal care at 10 weeks (p<0.001), 6 months (p<0.01) and 12 months (p<0.05); Usual activities at 6 (p<0.01) and 12 months (p<0.05); Pain/discomfort at baseline (p<0.05); Anxiety/Depression at baseline (p<0.05) and health today at baseline (p<0.01), 10 weeks (p<0.05) and 12 months (p<0.05). The exception was for Pain/discomfort were the more motivated were more likely to report higher (negative) scores of pain after 10 weeks (p<0.05).

The control for baseline score for the respective EQ-5D variables all yielded positive and significant scores at all measurement points (p<0.001)

Education is not significant at any of the EQ-5D variables with the exception for mobility. At baseline those with high education more likely to report troubles with mobility (p<0.01) but after 6 months it is reversed (p<0.05).

Sense of coherence

There were no significant treatment effects in SOC, although at six months the results show that the difference between the groups is border significant (CI:-032, 5.45, p=0.08, see table 2). The older aged participants have higher score at baseline (p<0.001) and those who are more motivated are scoring higher at baseline and after 6 months (p<0.01 and p<0.05 respectively). The baseline score of SOC yield positive and significant score after 10 weeks, 6 and 12 months (p<0.001).

Positive mental health (MHC-SF).

For positive mental health, the analysis shows that there are no significant differences between reablement group and control group at any measurement point, although border significant at ten weeks (p<0.09).

Older people report better scores at baseline and after 10 weeks (p<0.01 and p<0.05 respectively). At baseline the more motivated are scoring significantly higher (p<0.001).

Baseline score on positive mental health give statistical significance (p<0.001) on all measurements and the correlation is negative. Those with higher score on baseline report lower score on follow-ups and those with lower positive mental health score at baseline score higher on follow-ups.

Discussion

Both nationally and internationally, this study of reablement includes the largest number of municipalities ever undertaken. The study showed that reablement produced a significantly better effect for participants with respect to performance of and satisfaction with performance in daily activities, physical function, and health-related quality of life at 6 months follow-up, compared to usual care. Although the differences between the intervention and control groups declined over time, the improvements for the reablement group compared to the control group are significant after six months in the primary outcomes and on most of the secondary outcomes except for the subscales in EQ-5D; pain/discomfort and anxiety, SOC (indeed border significant) and MHC. After 12 months there were still significant treatment effects in total score on SPPB and the subdimension sit to stand and in the primary outcome COPM-P and in the secondary outcome subdimension in EQ-5D: usual care, the treatment effects were border significant. However, the results at 12 months follow-up are more uncertain, due to fewer participants particularly in the control group (n= 54). According to the power analysis it

was estimated that we needed to include at least 70 in the control group and 260 in the intervention group. Lack of power in the control group might explain that the differences between the groups in the main outcomes COPM and some secondary outcomes at 12 months not were significant.

The present studies' findings are in line with the three reviews that found limited improvement in favour of reablement regarding ADL (Cochrane et al, 2016, Whitehead et al, 2015, Sims-Gould et al, 2017). When it comes to physical functioning, our study showed promising result also in a twelve month perspective and thus support other studies that revealed effect in physical functioning (Parsons et al, 2013, Tinetti et al, 2002, Lewin et al, 2010). Regarded health related quality of life our study support that reablemet might improve this outcome and thus support the studies that claim that there is a tendency in favour of reablement (Tessler et al, 2016, Cochrane et al, 2016, Pettersson and Iwarsson, 2017, Parsons et al, 2012, Glendenning et al, 2010).

It is reasonable to expect that the reablement focus on meaningful activities, selfmanagement, participation in shaping outcomes and optimizing capacity (Moe et al, 2016, Winkel et al, 2015,) promote sense of coherence (Antonovsky,1987, Langeland et al, 2016). However, in the present study, sense of coherence was not significantly improved, although border significant at six months. However, the mean SOC score at the baseline was 68.4 points. This value is approximately the same that is observed in a comparable Swedish general population sample (mean 68.2 points) (Nilsson et al, 2010), suggesting that the potential for improving these participants' SOC is lower. In addition earlier research have also revealed that SOC is strongly and negatively associated to emotional distress including anxiety, anger, and depression (Erikson and Lindstrøm, 2006) and that SOC is specially related to mental health (Erikson and Lindstrøm, 2005). Although mental health issues not were exclusion criteria in the present study, the participants in the present study reported mainly physical health challenges. These factors might explain why sense of coherence not was strengthened and might also be the reason for that there were no significant changes in positive mental health.

The effect findings in the present study support the theory of optimising capacity. The theory of optimising capacity is a newly developed concept within reablement that purports to explain how various strategies are used to optimise the function of the older adults making them able to age in place (Moe et al, 2016). Optimising capacity signifies making the best out of each

person's resources, despite functional limitations. The identified strategies: appreciating a push, physical strengthening, adapting the environment, and building confidence, describe how the person become able to live in their own homes. Appreciating a push means accepting the motivational work of the healthcare providers and accepting the reablement service offered. Physical strengthening implies training in physical fitness and everyday life activities in order to increase physical capacities. Adapting the environment focuses on modifying the home and outdoor environments in order to optimize function. Building confidence, a process that runs parallel with the others, is based on rehearsal of activities and exercises, increased knowledge and support from others (Moe et al, 2016). Together, it is reasonable to think that these strategies lead to optimal functioning as stated by the theory, making the persons able to manage as well as possible in their own homes.

The findings in the present study suggest that motivation, gender, and age matter. The fact that motivation has impact is not surprising. Motivation creates energy and positive expectations and the barriers to such as physical activity might thus be diminished (Benjamin et al, 2014). Further, research show that distinct personalized goals in reablement create and promote motivation (Newton, 2012). The fact that the prioritized activities have been as a basis for developing rehabilitation goals, thereby enhancing communication and giving an active role to the participants in the rehabilitation process, create motivation (Hjelle et al, 2016). Furthermore, applying a person-centered instrument such as COPM promote participation and motivation (Wressle, 2002). In the present study this might be the case in both groups since both groups had the COPM interview. Furthermore, participation in the reablement program might create additional motivation for many reasons. It may be exciting to participate in something new because health personnel might convey expectations that this will produce results. Appreciating a push means accepting the motivational work of the healthcare providers and accepting the reablement service offered (Moe et al, 2016).

In the present study females improves in general more than men. This is compatible with research that show that there are sex differences in many health-related aspects, for instance in longevity in old age (World Health Statistics, 2014) and research that reveal that there are sex differences in morbidity among older people (Luppa et al, 2009).

Although the inclusion criteria regarding age was age 18 or older, the recruitment gave a sample of advanced age with a mean age of 78 years. Therefore, with the main proportion of the sample being old, it was not possible to provide reliable results regarding association between age and COPM outcomes although the present study indicates some trends for example that younger

participants report better at baseline and improve more in physical functioning than older participants. However, the present study does support that reablement might be offered to people of all ages, as maintained also by Aspinal et al, 2016. Another challenge is that the baseline COPM interview and scoring process might have had a therapeutic effect, independent of the forthcoming interventions (Sturkenboom et al, 2014, VanLeit et al, 2002). The COPM interview may promote consciousness and motivation, and thus a process of change might also start in the control group, thereby diminishing the

potential differences between the control and intervention groups.

The present study had some methodological challenges. Compliance with the intervention and data collection procedures comprises a possible threat to the reliability of the study. This was a great challenge because a large number of municipalities have been involved, as well as many different health care professionals. The reablement intervention is also individually tailored, which further increases the complexity. To ensure compliance with the study procedures, all municipalities have received training. Furthermore, we have ensured that if a health professional left the study, then their replacement has received sufficient training in both the intervention and the data collection procedures. In addition, the principal investigator has had regular contact with each municipality to ensure compliance with the procedures. The principal investigator has also checked all of the incoming data material continuously to detect any misunderstandings and missing values, which have been corrected accordingly, if possible. This indicate that the reliability of the study is good.

The intervention group reported consistently lower values on the clinical goals in COPM-P and COPM-S than the control at baseline, while there were no significant differences on baseline on health related quality of life, physical functioning, coping (SOC) and mental health (MHC). The fact that they were significantly lower on the main outcome measure of startup may indicate that participants in the control group generally had a higher level of functioning than the intervention group and therefore it may have been a selection bias. In addition, there is a greater dispersion of (cf. confidence interval COPM) in every measurement point. This means that participants in the two groups are different in some respects and it is therefore more uncertain results than it had been if this had been a randomized controlled trial. It is however a strength that we have controlled for differences between the groups at baseline for both COPM-P and COPM-S in the mixed analysis.

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The study was limited by drop-outs during the trial period. This is a common when conducting clinical controlled trials with long-term follow-up. At 12 months follow-up the drop-out rate was 26 %. The most common reasons for drop-out were health deterioration and/or place in nursing home or hospital. Thus it might have been a selection effect. However, if ethical possible, the respondents were asked to answer the questionnaire even if the dropped out of the intervention (intention to treat analysis). Furthermore, there was no significant difference at baseline on the primary outcome between those who dropped out at 12 months and those that completed the study. In addition, the mixed model analysis is robust to missing values, because data at all time-points are used, even if participants are missing at one of the follow-ups (Hox, 2002). However, an important strength is that this study occurs in natural settings; hence, its practicality, feasibility and, to some extent, generalizability may be high. In addition, the fact that the participants comprise a heterogeneous group from different parts of Norway also strengthens the generalizability of the results.

In summary, this clinical controlled trial demonstrates that reablement had significant effect on different outcomes after six months. After 12 months the effects decreases, indicating a need for follow-up interventions in the reablement group. The present study makes an important contribution to our knowledge of rehabilitation approaches for community-dwelling adults.

However, there is a need for more research on the effect of reablement in different populations including people with mental health challenges and on various outcomes including sense of coherence. In addition, we need more effect studies specially when several municipalities have implemented reablement as a regular service.

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Table 3. Mixed analysis with change in respectively COPM-P and COPM-S, SPPB, EQ-5D, SOC and MHC-SF as dependent variables and age, sex, education, motivation and group as independent variables

Independent variables	Unst	CO andardized	PM-P ¹ beta coef	COPM-S ¹ Unstandardized beta coefficients				
	Baseline	10 weeks	6 months	12 months	Baseline	10 weeks	6 months	12 months
Age	0.01	0.01~	0	0.01	0.02***	0.02*	0	0.01
Female (1=female, 0=male)	-0.18	0.41*	0.40*	0.65*	-0.12	0.51**	0.37~	0.67*
High education (1=high education, 0 = low education)	0.02	-0.26	0	0.27	0.09	-0.22	-0.07	0.34
Motivation (1=Not motivated, 10 = Very motivated)	-0.12***	0.18***	0.24***	0.19**	-0.15***	0.16***	0.24***	0.16*
Intervention (1=intervention, 0 =control group)	-0.48*	1.46***	1.23***	0.76~	0	1.31***	1.17***	0.59
Baseline score		0.23***	0.14*	0.20*		0.30***	0.26***	0.26**
Constant	4.43***	1.58*	2.41**	2.32*	3.34***	1.52*	2.24*	2.80*
Observations	810	680	630	340	808	678	625	340
Number of groups	42	42	41	38	42	42	41	38

*** p<0.001, ** p<0.01, * p<0.05, ~ p<0.10 ¹ Scale 1-10, 10 is best.

	SPPB total-score ¹			SPPB balance ²			SPPB walking ²				SPPB Sit-to-stand ²					
	Baselin e	10 weeks	6 months	12 months	Baselin e	10 weeks	6 months	12 months	Baselin e	10 weeks	6 months	12 months	Baselin e	10 weeks	6 months	12 months
Age	- 0.04***	-0.01	-0.03**	-0.04**	- 0.02***	0	-0.01~	-0.01*	- 0.01***	0	-0.01**	-0.01*	- 0.01***	-0.01*	-0.01***	-0.03***
Female (1=female, 0=male)	-0.2	0.07	0.50*	0.60~	0.03	-0.05	0.15	0.2	-0.13	0.09	0.19*	0.18	-0.12	0.08	0.14	0.29*
High education (1=high education, 0 = low education	0.51*	0.12	0.37	1.13**	0.16	-0.03	0.03	0.39*	0.12	0.11	0.24*	0.34*	0.19*	0.18~	0.17	0.52**
Motivation, 1=Not motivated at all – 10 = Very motivated	0.09~	0.16***	0.12**	0.1	0.03	0.08***	0.04*	0.04	0.03	0.04*	0.06**	0.06*	0.03	0.06**	0.03	0
Intervention (1=intervention, 0 =control group)	-0.89**	1.26***	1.16***	0.93*	-0.19	0.31*	0.33**	0.12	-0.34*	0.35**	0.34*	0.13	-0.31*	0.57***	0.44***	0.47*
Baseline score		0.76***	0.73***	0.65***		-0.45***	-0.51***	-0.55***		-0.36***	-0.42***	-0.53***		-0.24***	-0.27***	-0.40***
Constant	8.55***	1.35	2.61**	3.92**	3.44***	1.03**	1.42***	1.76***	3.04***	0.86*	1.13**	1.49**	2.05***	0.49	1.26**	2.37***
Observations	800	667	614	324	800	666	613	324	800	663	613	323	799	662	612	323
Number of groups	42	42	41	38	42	42	41	38	42	42	41	38	42	42	41	38

*** p<0.001, ** p<0.01, * p<0.05, ~ p<0.10 ¹ Scale 0-12, highest is best ²Scale 0-4, highest is best

		Mobility	(EQ-5D) ¹		Personal care (EQ-5D) ¹				Usual activities (EQ-5D) ¹			
	Baselin e	10 w eeks	6 months	12 months	Baselin e	10 w eeks	6 months	12 months	Baselin e	10 w eeks	6 months	12 months
Age	-0.01***	-0.01**	0	-0.01*	-0.01~	0	0	0	-0.01**	-0.01	0	-0.01
Female (1=female, 0=male)	-0.04	0	-0.18*	-0.30*	-0.04	-0.03	-0.13~	-0.23*	0.08	0.14	0.01	-0.25*
High education(1=higheducation,0=low education	0.25**	0.1	-0.20*	-0.21	0.04	0.05	-0.08	-0.12	0.03	0.01	-0.02	-0.24~
Motivation, 1=Not motivated at all – 10 = Very motivated	-0.01	-0.05**	-0.03~	-0.05~	-0.02	-0.05***	-0.07***	-0.05*	0	-0.06~	-0.06**	-0.06*
Intervention (1=intervention, 0 =control group)	0.21*	-0.46***	-0.34***	-0.19	0.22~	-0.32***	-0.19*	-0.22~	0.11	-0.23	-0.23*	-0.24
Baseline score		0.45***	0.44***	0.38***		0.42***	0.32***	0.34***		0.26***	0.36***	0.40***
Constant	3.60***	2.51***	2.16***	2.97***	2.38***	1.52***	1.87***	1.72***	3.43***	2.72***	2.09***	2.48***
Observations	800	667	626	336	801	669	627	337	800	664	625	338
Numberofgroups	42	41	41	38	42	41	41	38	42	41	41	38

*** p<0.001, ** p<0.01, * p<0.05, ~ p<0.10 ¹Scale 1-5, low is best

	Pain/discomfort (EQ-5D) ¹					Anxiety /Depression (EQ-5D) ¹				Health today (EQ-5D) ²			
	Baselin e	10 w eeks	6 months	12 months	Baselin e	10 w eeks	6 months	12 months	Baselin e	10 w eeks	6 months	12 months	
Age	-0.01**	-0.01*	-0.01**	-0.01**	-0.02***	-0.01*	0	0	0.40***	0.16*	0.09	0.08	
Fem ale (1=female, 0=m ale)	0.24**	0.14~	0.13	0.12	0.20**	0.02	0.03	0.03	-0.7	-0.85	2.22	5.93*	
High education(1=higheducation,0=low education	0.09	-0.12	-0.16~	-0.19	0	-0.07	-0.06	0.03	0.45	0.54	-0.04	3.79	
Motivation, 1=Not motivated at all – 10 = Very motivated	-0.04*	0.04*	0.01	-0.01	-0.05**	0	0	-0.03	0.90**	0.71*	0.51	1.19*	
Intervention(1=intervention,0=controlgroup)	0.01	-0.07	-0.11	-0.02	0.20*	0.11	-0.04	0.02	-3.79~	5.24**	7.04**	2.1	
Baseline score		0.45***	0.49***	0.44***		0.52***	0.45***	0.44***		0.40***	0.41***	0.40***	
Constant	3.60***	1.58***	1.91***	2.21***	3.40***	1.14***	1.18***	1.12**	15.19*	15.52*	19.07**	15.54~	
Observations	797	665	621	335	796	660	610	330	792	664	613	331	
Number of groups	42	41	41	38	42	41	41	38	42	42	41	38	

*** p<0.001, ** p<0.01, * p<0.05, ~ p<0.10 ¹Scale 1-5, low is best ² Scale 0-100, high is best

	Baseline	10 weeks	6 months	12months
Age	0.27***	0.05	0.06	0.03
Female (1=female, 0=male)	-0.88	-0.74	0.75	-1.07
High education (1=high education, 0 = low education	-0.27	1.60~	1.65	0.4
Motivation, 1=Not motivated at all – 10 = Very motivated	0.56**	0.27	0.44*	-0.2
Intervention (1=intervention, 0 =control group)	-1.24	1.46	2.56~	0.51
Baseline score		0.56***	0.53***	0.54***
Constant	44.68***	23.20***	21.22***	31.31***
Observations	762	631	579	302
Number of groups	42	42	41	38

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*** p<0.001, ** p<0.01, * p<0.05, ~ p<0.10 ¹ Scale 13-91, high is best.

	MHC_SF ¹						
	Baseline	10 weeks	6 months	12 months			
Age	0.13**	0.10*	-0.02	-0.07			
Female (1=female, 0=male)	1.38	1.36	0.59	0.34			
High education (1=high education, 0 = low education	1.69	-1.01	2.15~	0.43			
Motivation, 1=Not motivated at all – 10 = Very motivated	1.05***	0.36	0.06	0.31			
Intervention (1=intervention, 0 =control group)	-0.68	2.07~	2.19	2.56			
Baseline score		-0.46***	-0.46***	-0.53***			
Constant	23.94***	12.20**	20.02***	25.87***			
Observations	688	506	508	266			
Number of groups	42	40	41	37			

*** p<0.001, ** p<0.01, * p<0.05, ~ p<0.10 ¹Scale 0-70, high is best