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Analyzing change processes resulting from a smartphone maintenance intervention based on Acceptance and Commitment Therapy for women with Chronic Widespread Pain.

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ABSTRACT

PURPOSE

This study investigated change processes resulting from a smartphone maintenance intervention with daily electronic diaries and personalized written feedback based on Acceptance and Commitment Therapy following a rehabilitation program for patients with chronic widespread pain.

METHODS

The RCT included 48 women who, during a 5-week period, completed electronic diaries 3 times daily, totaling 3372 entries. In response to the completed diaries they received daily feedback from a therapist during 4 weeks, except during weekends, totaling 799 feedback messages. To analyze the change processes resulting from the smartphone intervention, we explored the associations between feedback and daily ratings of participant's physical activities, positive emotions, fear avoidance, acceptance and self-management. Commitment to physical activities and the participants' evaluation of feedback were also analyzed. Multilevel models were used in the statistical analyses.

RESULTS

Participants' average "pain fear and avoidance" decreased over the intervention period (Mean -0.019, $P = 0.05$). Self-management, pain acceptance and positive feelings increased (Mean -0.030, $P < .01$, Mean -0.015, $P = < .01$ and Mean -0.011, $P = 0.01$). Participants' performance of physical activities decreased slightly over time, but the level of commitment was high and they evaluated the feedback as supportive for staying sufficiently active. No correlation between diary contents and feedback messages was found, even though most of the participants evaluated the feedback as supportive.

CONCLUSIONS

No support for a relationship between ACT consistent diary content and feedback was found. However, diary measures were consistent with the ACT model and may have influenced positively the change processes.

INTRODUCTION

Recommended treatments of chronic widespread pain (CWP) involve multidisciplinary approaches due to the complex pathophysiological mechanisms of this disease combined with social and psychological factors [1, 2]. These treatments include graded physical exercises, pharmacological treatment and cognitive behavioral therapy, (CBT) often provided within the frame of multidimensional rehabilitation [3-5]. Although the short-term effects (up to 1 year) of such treatments are well demonstrated, interventions to support the maintenance of effects and avoiding relapses are needed [3]. For treatment and/or maintenance treatment of CWP an alternative may be internet CBT and smartphone interventions [6, 7]. Such technology-supported interventions are increasingly used to support people with health problems including chronic pain in self-management, and show effects similar to that of face-to-face CBT [8-15]. Studies that, in addition to internet CBT, which have used methods of communicating with participants, such as short message service (SMS), appear to be even more effective in supporting behavioral change [16].

A relatively recent development within CBT with strong empirical support is Acceptance and Commitment Therapy (ACT). The objective of ACT is to improve functioning and quality of life by increasing psychological flexibility (PF) [17-19]. PF is defined as the ability to act in accordance with long-term goals and values also in the presence of interfering pain and distress. In the ACT treatment model, PF comprises sub-processes such as acceptance, defusion, values orientation, committed actions, present moment awareness and self as context [20, 21]. ACT shares important features with CBT, such as behavior activations, although acceptance and cognitive defusion strategies may be relatively unique for ACT [20, 22]. Several studies based on ACT have demonstrated effects related to improvement of health outcomes in patients with chronic pain [18, 23-26], including internet-based interventions [27-29]. Studies have also investigated the impact of the different treatment components of ACT [26] as well as mediators of change, supporting the importance of both ACT consistent interventions and changes in processes related to PF [18]. However, to our knowledge, no study has yet investigated the change process of the core components of ACT resulting from a smartphone intervention.

The current paper builds upon a RCT smartphone maintenance intervention (SMI) with electronic diaries and therapist written feedback based on an ACT model to support women with chronic widespread pain after completing a 4-week rehabilitation program [28, 30].

The aim of the present study was to investigate the change processes resulting from the SMI. For this purpose, the associations between daily electronic diaries content and daily written personalized feedback were analyzed based on the following research questions:

1. Did participants' daily planned and performed physical activities, positive feelings, pain acceptance and self-management increase during the intervention period? Were these changes related to the daily feedback?
2. Did participants' pain related fear and avoidance and catastrophizing decrease during the intervention period? Were these changes related to the daily feedback?
3. Were participants committed to and satisfied with their planned physical activities?
4. How did the participants evaluate the daily individualized feedback?

MATERIAL AND METHODS

Design

The design was a two-arm randomized controlled trial. All participants completed a four-week inpatient multidimensional rehabilitation program for chronic pain including education and pain management in a cognitive setting, various forms of aerobic exercises, stretching, myofascial pain treatment, relaxation and medication as needed [31]. In the fourth week of the rehabilitation program participants were randomized to one of the two study arms: experimental group or control group. The experimental group received four weeks of SMI. The main elements of the SMI were: A personal meeting, daily electronic diaries and individualized written situational feedback.

In the personal meeting each participant was informed about the intervention and asked about her functioning, goals for health-related behavior and needs for support. Values and value-based activities were discussed and the patient received two written value-based exercises to take home. The participant was lent a smartphone and made the first diary entry at the meeting. The therapist received a summary of this first meeting.

The participants were asked to complete electronic diaries 3 times per day (morning, midday and evening) for five weeks. The primary objective during the first week of completing diaries was to familiarize the participants with the technology. The diaries included 16 to 24 questions about planned and performed physical activities (i.e. mild exercise, stretching, resting, aerobic exercise, pleasurable activity), satisfaction with performed activities, thoughts, feelings, sleep, pain level, pain-related fear and avoidance, pain catastrophizing, pain acceptance, pain self-management and evaluation of the feedback (see Table 1). All diaries included a comment field giving participants the opportunity to write a short personal message to the therapist. If the diary entry was not returned within 45 min, the server automatically sent an SMS reminder message. Two reminders within 1 h per diary were allowed. The submission of the diary was only possible when it was fully completed within 90 minutes. Then the diary was closed

Table 1. Examples of diary content and timing with analyzed variables

Diary Content	Variable	MD	RD	ED	Example of statements (S) with it quantity and answers (A) with alternatives
1. Planned Physical Activity	PLA PMA PHA	x	x		S: Until the next diary, I plan to... A: List of activities to choose from including low, medium and high level activities respectively (1.Horizontal exercise, 2.Relaxing, 3.Stretching, 4.Exercise in slow tempo and 5.Aerobic exercise).
2. Executed Physical Activity	ELA EMA EHA		x	x	S: Since the last diary I have done... A: List of activities to choose from including low, medium and high level activities respectively (1.Horizontal exercise, 2.Relaxing, 3.Stretching, 4.Exercise in slow tempo and 5.Aerobic exercise).
3. Evaluation Physical Activity	EPA			x	S: I am ... with today's activity level A: Five-point Likert scale (0.Very satisfied, 1.Satisfied, 2.Neutral, 3.Unsatisfied, 4.Very unsatisfied).
4. Pain Catastrophizing	PC		x		S: 1. Right now I worry about whether the pain will end, 2. Right now I feel that there's nothing I can do to reduce the intensity of the pain and 3. Right now it feels like I can't stand the pain anymore. A: Five-point Likert scale (0.Agree completely, 1.Agree, 2.Not sure, 3.Disagree, 4.Disagree completely).
5. Pain Acceptance	PA		x		S: Right now I feel my life is going well, even though I have chronic pain A: Five-point Likert scale (0.Agree completely, 1.Agree, 2.Not sure, 3.Disagree, 4.Disagree completely).
6.Pain Fear and Avoidance	PFA		x		S: 1. Right now I don't dare to move a lot because of the pain, 2. Right now I try to avoid activities that cause pain, 3. Right now I am afraid of the pain and 4. Right now I believe it is dangerous for me to move my body. A: Five-point Likert scale (0.Agree completely, 1.Agree, 2.Not sure, 3.Disagree, 4.Disagree completely).
7. Pain Self-Management	PSM		x		S: 1. Right now I use what I've learned to help keep my pain under control, 2. Right now I cope well with the pain, 3. Right now I do what I want, even though it causes increased pain or makes the pain reappear, 4. Right now I'm using some strategies to help me better deal with my pain problems and 5. Today I was able to do what I wanted and needed despite the pain. A: Five-point Likert scale (0.Agree completely, 1.Agree, 2.Not sure, 3.Disagree, 4.Disagree completely).
8. Positive Feelings	PF	x		x	S: Right now I am (1.In a good mood, 2.Grateful, 3.Relaxed, 4.Satisfied and 5.Enthusiastic) A: Five-point Likert scale (0.Agree completely, 1.Agree, 2.Not sure, 3.Disagree, 4.Disagree completely).
9. Feedback Evaluation	FE			x	S: The feedback has helped me ... A: List of answers to choose from (1.To stay suitably active, 2. Be aware of my feelings, 3.Stay positive, 4. Be aware of my coping strategies, 5.The feedback was not helpful today, 6. Received no feedback today and 7. Something else)
Total number of items in the different diaries		18	27	24	

Legend: MD=Morning Diary; RD=Random Diary; ED=Evening Diary; PLA=Planned Low Level Activity; PMA=Planned Medium Level Activity; PHA=Planned High Level Activity; ELA=Executed Low Level Activity; EMA=Executed Medium Level Activity; EHA=Executed High Level Activity; EPA=Evaluation of Physical Activities; PC=Pain Catastrophizing Statements; PA=Pain Acceptance Statement; PFA=Pain Fear and Avoidance Statements; PSM=Pain Self-Management Statements; PF=Positive Feelings; FE=Feedback Evaluation

For four weeks (excluding weekends), after returning home, participants received daily written feedback messages written by one of three therapists who were trained in ACT. The feedback messages were individualized and tailored to the participant's situation as reported in the diary, based on the summary of personal information given at the personal introductory meeting (i.e. family situation and health-related goals) and formulated in accordance with the ACT - protocol developed for the study [32] focusing on values, value-based behavior, mindfulness and acceptance. The protocol was based on ACT for chronic pain [22, 33, 34]. All ACT processes (values, committed action, contact with the present moment, cognitive defusion and acceptance) were present in each of the four weeks, but with different focus. The first week was used to introduce the ACT processes and the following weeks were used to reinforce the given information, to go gradually in depth and to stimulate the practice of exercises related to the ACT processes. [32]. Despite of the existence of a protocol, it's important to emphasize that the feedback messages were tailored and formulated based on input from the first meeting with the participants, daily e-diaries and the ACT theory. The therapist had the freedom to evaluate and choose the ACT component(s) that suited the participant at that specific moment. In addition, the therapists were instructed to be empathic, include positive reinforcement, information, metaphors and ACT exercises. The instructions for the exercises were written directly in the feedback or the feedback referred to exercises available on the mobile phone and/or the website. The therapists also had access to each other's responses. The feedback was intended to support and stimulate self-management, encourage mindfulness and willingness to engage in meaningful activities to promote behavioral change (see Textbox 1 for examples of the feedback). The feedback messages were available 90 minutes after participants completed the midday diary during weekdays and were mainly based on the three last submitted diaries (the evening diary from the day before and the morning and midday diaries from the same day). Feedback was sent even if the midday diary was not submitted; then information from the last submitted diary was used. An SMS was sent to signal that feedback was available. The SMS included a link to the website where the feedback was posted. There was no limitation to the length of the feedback, which varied from a few sentences to a few paragraphs.

Textbox 1. Example of a feedback message

Hi. Congratulations on having managed to complete the four week intensive treatment at the rehabilitation center.

I suggest that you use a few minutes to think about how it feels to be finished with your stay at the rehabilitation center? What has changed? What is the most important thing that you have learned? Is there anything that you learned that you weren't sure you would manage to cope with? Now you are going towards a life with less pain and more activity - you've probably already changed some health habits - the challenge in the coming weeks will be to apply what you have experienced as useful at the rehabilitation center in everyday life at home. Especially now in the beginning, this will require some effort, but eventually it will become an established habit and will feel much less demanding.

It seems that you have planned an active day today, great that you also get to rest for a while and perform relaxation exercises in between. It does not seem like you have negative thoughts related to your pain now. It seems that it is you who decides what you do and your decision is not influenced by your pain experience.

That's positive! Have a nice afternoon together with your daughter and friends. Regards Mary

All participants received login information to a non-interactive website with information on coping strategies for people with chronic pain. The website also included four audio files with mindfulness exercises (e.g. focused breathing, awareness of thought content).

See Appendix 1 for more detailed information of the RCT

In the current study only data from intervention group; the diaries and the feedback were analyzed.

Sample

The analyses of the present study are based on data from participants who were randomized to the treatment condition (48 women, see Table 2) in a previously reported RCT [28]. Data consisted of de-identified daily diaries (totaling 3372) and written feedbacks (totaling=799).

Table 2. Sample characteristics at admission to the inpatient rehabilitation center

Characteristic	Smartphone intervention
Age, mean (SD), n	43 (11.12), 48
Marital status	
Married or cohabiting	66.7% (n=32)
Divorced	10.4% (n=5)
Single	18.8% (n=9)
Widow	2.1% (n=1)
Unknown	2.1% (n=1)
Years of education	
≤ 10 years (elementary)	16.7% (n=8)
11-13 years (high school)	22.9% (n=11)
>13 years (college/university)	52.1% (n=25)
Unknown	8.3% (n=4)
Employment status	
Working/studying	18.8% (n=9)
Unemployed	4.2% (n=2)
On sick leave	8.3% (n=4)
On disability pension	54.2% (n=26)
Part time working/studying and part time sick leave	10.4% (n=5)
Unknown	4.1% (n=2)
Diagnosed with fibromyalgia	85.4 % (n=41)
Duration of symptoms (years), mean (SD), n	12.66 (9.33) 45
Current VAS ^a rating (past couple of days) mean (SD) n	66.22(17.58) 48

^a VAS: visual analog scale, range 0-100

Assessment of daily diaries

Physical activities

The daily diaries had a list of activities to choose from for planned activities (morning and midday) and executed activities (midday and evening). Both planned and executed activities included low level activity (horizontal exercises, relaxing, and stretching) medium level activity (exercise in slow tempo) and high level activity (aerobic exercise). The variables constructed were Planned Activity (Low = PLA, Medium= PMA and High

level=PHA) and Executed Activity (Low = ELA, Medium =EMA, High = EHA). All responses were coded as 1 or 0. The activities were analyzed as dependent variables to measure change over time. All types of activities were analyzed separately, as was the time of delivery throughout the day (morning, afternoon and night). Furthermore, all activities of each type on each day were added to measure the total.

Evaluation of performed physical activities (EPA)

By analyzing this variable as a dependent variable, it was possible to ascertain how the participants' satisfaction with physical activities varied over time. The scale responses were coded from 0 (very satisfied) to 4 (very unsatisfied), see Table1.

Commitment with physical activities

By using the executed activity as dependent variable and planned activity as an independent variable in predicting the activity, it was possible to measure the patients' commitment.

Pain catastrophizing (PC)

Three statements from the Catastrophizing Pain Scale (PCS) were present in the random diary with five possible answers (0 'strongly agree' to 4 'strongly disagree'), i.e., the higher the score, the more the participants 'disagree' with the PC statements indicating less catastrophizing thoughts. The independent variable representing PC was a sum score from these three questions. See Table 1. By analyzing PC as a dependent variable, it was possible to evaluate how the participants' PC varied over time.

Pain acceptance (PA)

The statement "Right now I feel my life is going well, even though I have chronic pain" represented the pain acceptance. A five-point likert scale measured the responses from 0 'strongly agree' to 4 'strongly disagree', i.e., the lower the score, the more the patient 'agrees' with the statements. By analyzing this statement as a dependent variable, it was possible to evaluate how the participants' pain acceptance varied over time.

Pain fear and avoidance (PFA)

Four statements represented pain fear and avoidance. See Table 2. A five-point likert scale measured the responses from 0 'strongly agree' to 4 'strongly disagree', i.e., the lower the score, the more the participant 'agrees' with the statements. By analyzing the sum of the scores of these statements as a dependent variable, it was possible to evaluate how the participants' pain fear and avoidance varied over time.

Pain self-management (PSM)

Five statements represented the pain self-management. See Table 2. A five-point likert scale measured the responses from 0 'strongly agree' to 4 'strongly disagree', i.e., the lower the score, the more the patient 'agrees' with the statements. By analyzing the sum of the scores of these statements as a dependent variable, it was possible to evaluate how the participants' pain self-management varied over time.

Positive feelings (PF)

Five statements represented the positive feelings, e.g., 'right now, I am grateful'. A five-point likert scale measured the responses from 0 'strongly agree' to 4 'strongly disagree', i.e., the lower the score, the more the participant 'agrees' with the statements (Table 2). By analyzing the sum score of these statements as a dependent variable, it was possible to evaluate how the participants' positive feelings varied over time.

Evaluation of feedback

Participants' evaluation of feedback was also investigated. Each evening the participant could choose from a list of six statements. See Table 2; it was possible to choose all or to submit the diaries without answering these questions. During the first six days participants were at the rehabilitation center and did not receive feedback messages. Therefore the first week and the weekends were not included in the analyses of these variables

Assessment of feedback messages

In a previous study, the feedback messages were qualitatively analyzed based on an ACT and communication framework and a coding scheme/system was created [32]. Twelve codes were identified; five codes were related to an ACT model and seven codes were related to motivation and communication strategies. The ACT model codes were Values (V), Committed Action (CA), Present Moment (PM), Acceptance (AC) and Cognitive Defusion (CD); The motivation and communication codes were Behavioral Support (BS), Advice (Ad), Emphatic Statements (ES), Stimulate Participation (SP), Creative Communication (CC), General Information (GI) and Educational Information (EI) (examples given in Appendix 2) [32].

The previously developed coding scheme was used in the present study making it possible to include the feedback messages in the statistical analyses.

All possible ACT codes (V, CA, PM, AC and CD) and all possible motivation and communication codes (BS, ES, Ad, SP, CC, GI and EI) were included in the analyses as independent variables to measure their impact on the variables from the daily diaries.

Furthermore, three new feedback variables were created: Variable “A” condensing all ACT codes; Variable “M”, condensing all motivation and communication codes and variable “AM”, condensing all feedback codes. The intention was to subsequently measure the impact on the daily diaries of the entire ACT content, the entire motivation and communication content and the entire feedback message.

Statistical procedures

As mentioned before, the data from this study were collected up to three times daily over four weeks featuring repeated measurements. For this type of data, the Multilevel Models (MLM) are the best recommended statistical method due to its well documented advantages over other statistical methods [35]. Regarding internal consistencies analysis, the ordinal reliability test was applied. The ordinal alpha more accurately estimates reliability for ordinal item response data i.e. Pain Catastrophizing (PC), Pain Fear and Avoidance (PFA) and Pain Self-Management (PSM), than alternative methods [36]. For this study, the variables were analyzed using MLM with intercept and time slope as covariates, both as fixed and random effects. All calculations were done using an R statistical program. For the mixed models, the lme multilevel package was used and for internal consistencies analyses the Rcmdr, psych and GPArotation packages were used [37]. The correction for multiple testing was done using the Bonferroni test [38]. In the course of the study, there were no drop-out cases. For each of the results described below, the code was run as a standalone analysis, differing in the number of covariates and thus the results don't interact with each other.

RESULTS

After correction for multiple tests, no correlation was found between the diary content and the specific elements of the feedback messages. Thus details of these analyses are not included in this paper.

Physical activities

To measure how physical activities evolved over the intervention period, the variables that represent the Planned Low Level Activity (PLA) were added together and treated as a single untransformed variable. Analyzing PLA as a dependent variable resulted in the time slope parameter estimated at -0.029 with a P value < 0.01, which indicates that the decrease of this activity over time was statistically significant. The same procedure was applied for the analysis of the other Planned Activities (Medium= PMA and High level=PHA) and Executed Activities (Low = ELA, Medium =EMA, High = EHA). In five out of six models, the time effect was statistically

significant, however negatively for all models, which indicates that activities diminished over time, see Table 3.

Evaluation of performed physical activities (EPA)

The patients' own satisfaction with their physical activities has been studied. For this variable, no transformation was applied. In this case, lower values of the dependent variable represent more satisfaction with activities and the time parameter is negative (-0.012) and statistically significant (p-value < 0.01), showing that, over time, the participants became more satisfied with their physical activities, see Table 3.

Commitment with planned activities

By using the planned activities as a covariate to the performed activities, it is possible to study participants' commitment to their physical activities. The results show positive parameter estimates and p-values < 0.01 (Table 4), confirming that participants were committed to their planned activities (Figure 2, 3 and 4).

Table 3. Results of analyses of diary content

Diary Content	Variable	Intercept (I)	Time Slope (S)	I and S effects correlation	Residual SD
		Mean (RES D), <i>P</i> value	Mean (RES D), <i>P</i> value		
1. Planned Physical Activity	PLA	2.75 (1.16), <.01	-0.029 (0.044), <.01	-0.328	0.87
	PMA	0.44 (0.35), <.01	-0.004 (0.012), 0.16	-0.290	0.50
	PHA	0.39 (0.31), <.01	-0.009 (0.008), <.01	-0.520	0.42
2. Executed Physical Activity	ELA	2.19 (0.99), <.01	-0.029 (0.029), <.01	0.007	0.98
	EMA	0.32 (0.28), <.01	-0.004 (*), <.01	*	0.41
	EHA	0.31 (0.31), <.01	-0.007 (0.007), <.01	-0.724	0.38
3. Evaluation Physical Activity	EPA	2.58 (0.57), <.01	-0.012 (0.016), <.01	-0.366	0.82
4. Pain Catastrophizing	PC	6.30 (1.08), <.01	0.004 (0.029), 0.46	-0.422	0.86
5. Pain Acceptance	PA	2.28 (0.72), <.01	-0.011 (0.017), 0.01	0.0830	1.30
6. Pain Fear and Avoidance	PFA	6.75 (1.36), <.01	-0.019 (0.057), 0.05	-0.3840	1.34
7. Pain Self-Management	PSM	9.04 (1.29), <.01	-0.030 (0.039), <.01	-0.1050	1.53
8. Positive Feelings	PF	2.37 (0.69), <.01	-0.015 (0.025), <.01	-0.393	1.01

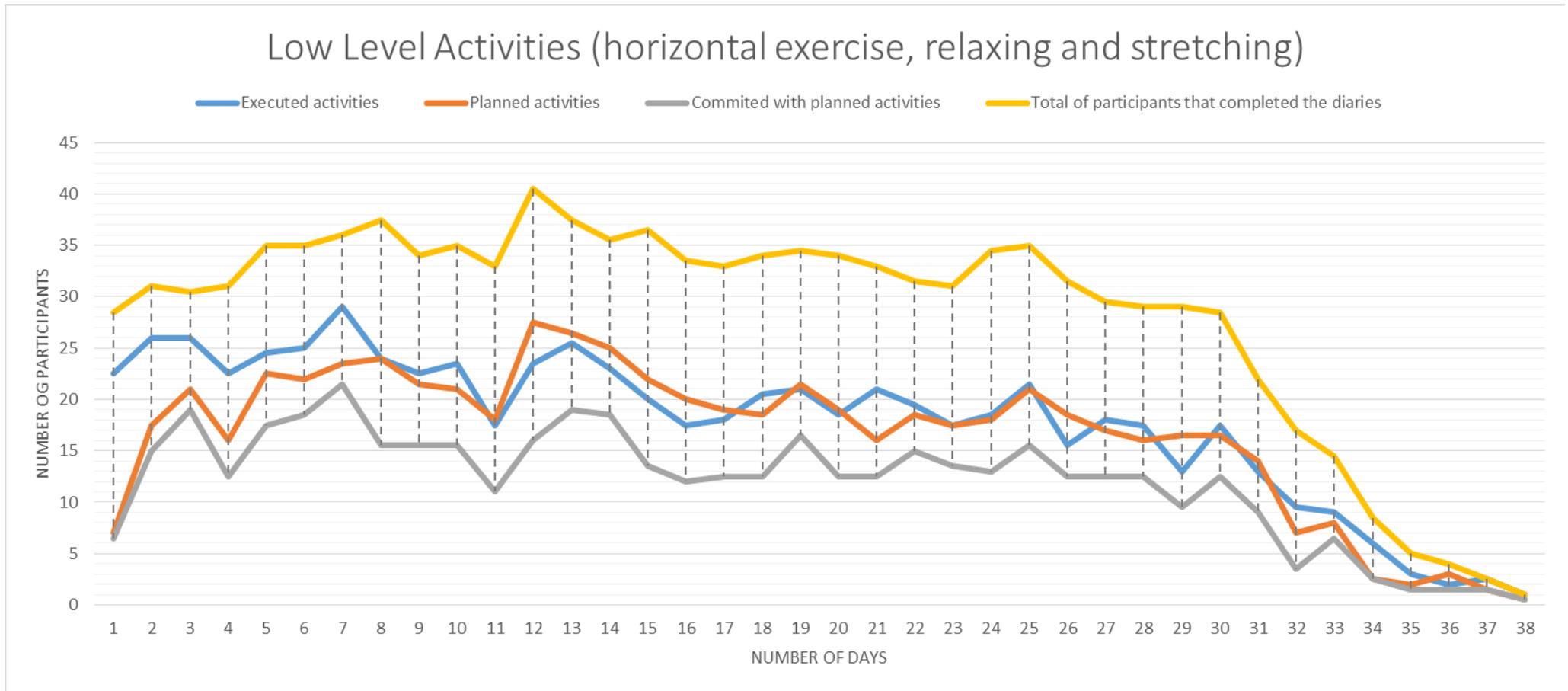
Legend: SD = Standard Deviation; RESD = Random Effect SD; MD=Morning Diary; RD=Random Diary; ED=Evening Diary; PLA=Planned Low Level Activity; PMA=Planned Medium Level Activity; PHA=Planned High Level Activity; ELA=Executed Low Level Activity; EMA=Executed Medium Level Activity; EHA=Executed High Level Activity; EPA=Evaluation of Physical Activities; PC=Pain Catastrophizing Statements; PA=Pain Acceptance Statement; PFA=Pain Fear and Avoidance Statements; PSM=Pain Self-Management Statements; PF=Positive Feelings.

* Random effect did not converge and was removed from the model

Table 4. Effect analysis of Planned and Executed Physical Activities

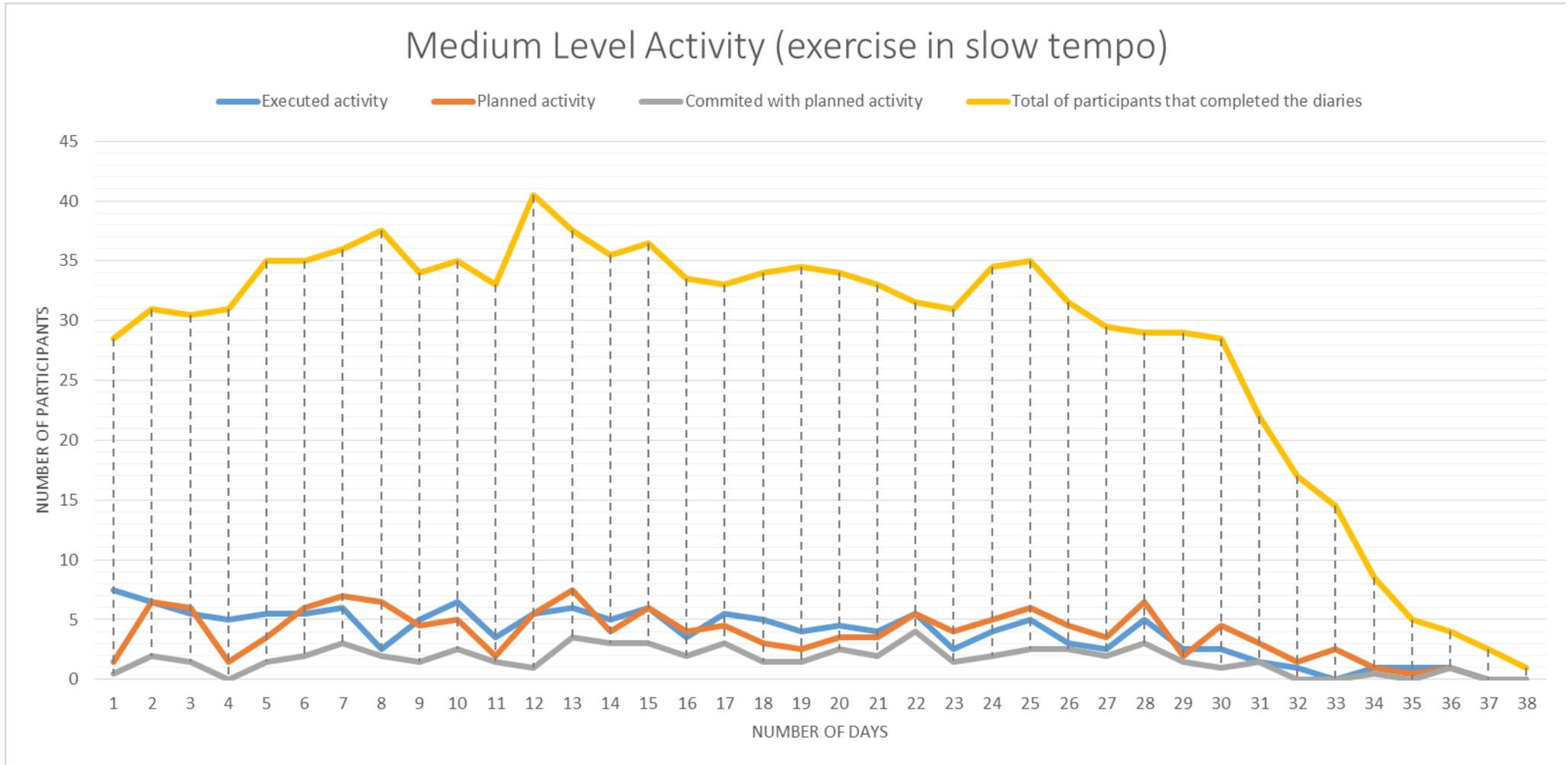
Dependent variable	Independent variables	Coefficient estimate	P-value	Residual SD
Midday Executed Low Level Activity	Morning Planned Low Level Activity	0.47	< .01	0.592
Evening Executed Low Level Activity	Midday Planned Low Level Activity	0.27	< .01	0.625
Midday Executed Medium Level Activity	Morning Planned Medium Level Activity	0.34	< .01	0.270
Evening Executed Medium Level Activity	Midday Planned Medium Level Activity	0.31	< .01	0.269
Midday Executed High Level Activity	Morning Planned High Level Activity	0.52	< .01	0.249
Evening Executed High Level Activity	Midday Planned High Level Activity	0.46	< .01	0.224

Figure 2: Mean of low level activities by number of participants that answered the diaries per day



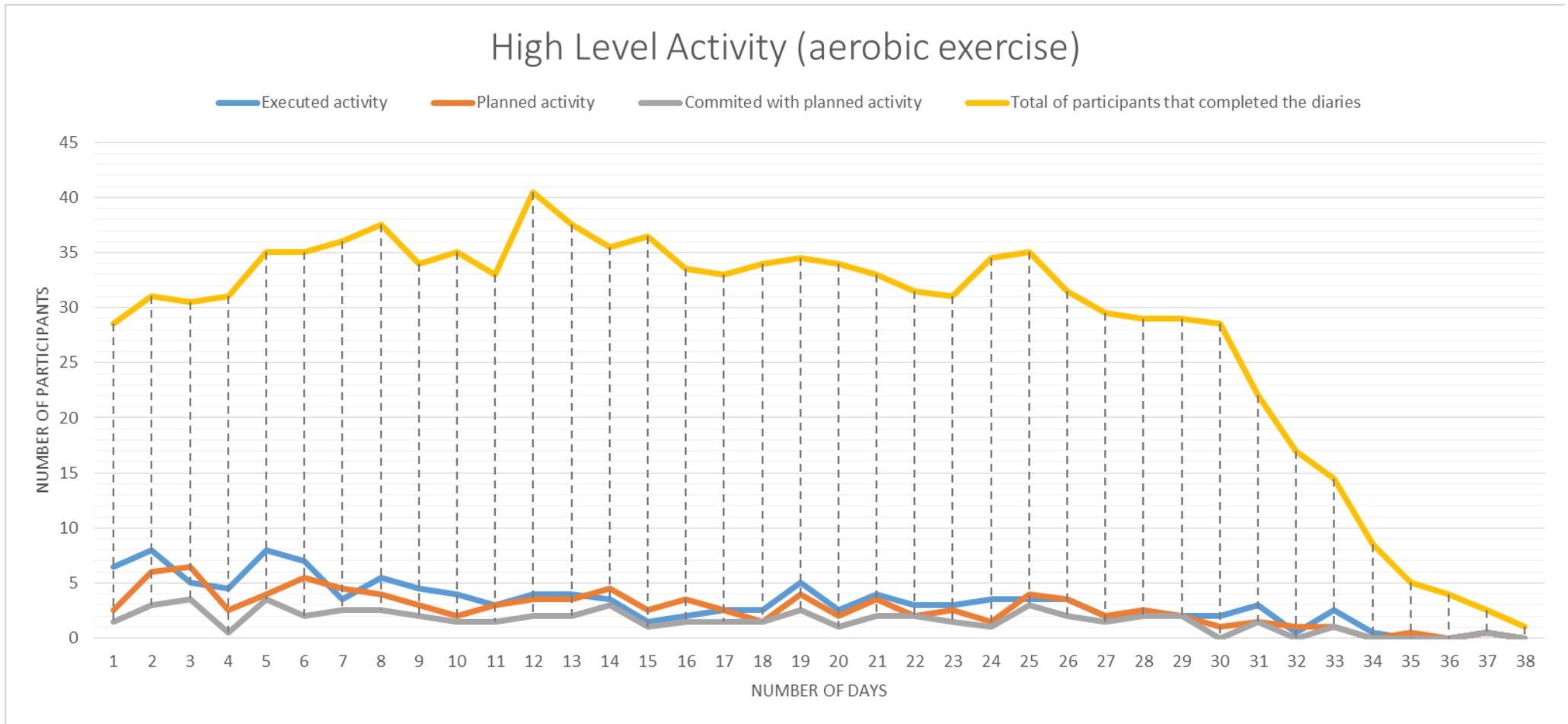
Legend: Executed activities = Refers to the participants that executed low level activities; Planned activities = Refers to participants that planned to execute low level activities; Committed with planned activities = Refers to participants that have planned and executed the planned activities.

Figure 3: Mean of medium level activities by number of participants that answered the diaries per day



Legend: Executed activity = Refers to the participants that executed medium level activity; Planned activity = Refers to participants that planned to execute medium level activity; Committed with planned activity = Refers to participants that have planned and executed the planned medium level activity.

Figure 4: Mean of high level activities by number of participants that answered the diaries per day



Legend: Executed activity = Refers to the participants that executed high level activity; Planned activity = Refers to participants that planned to execute high level activity; Committed with planned activity = Refers to participants that have planned and executed the planned high level activity.

Pain Catastrophizing (PC)

The internal consistency for the PC- items was acceptable (ordinal alpha coefficient 0.79). By using the sum of the PCS score as the dependent variable, its dynamics could be evaluated. The parameter estimate for time slope was positive (0.004), which means that as time passes more participants 'disagree' with the PC statements indicating a reduction in catastrophizing thoughts over time, although changes were not statistically significant (p-value of 0.46), see Table 3.

Pain acceptance (PA)

By modeling the untransformed pain acceptance as the dependent variable, it is possible to verify how it changes over time. This variable has lower values the more the patient agrees with the pain acceptance statement. The parameter estimate for time is negative (-0.011) with a p-value of 0.01, showing that PA increases significantly over time (Table 3).

Pain fear and avoidance (PFA)

The internal consistency for PFA - items was acceptable (ordinal alpha coefficient 0.78). This variable was analyzed after re-coding one out of four items (0= strongly disagree to 4= strongly agree). This item was inverted for the data collection. The lower values indicated lower PFA. The time parameter estimate was negative (-0.019) with a p-value of 0.05, showing that fear and avoidance significantly diminished over time (Table 3).

Pain self-management (PSM)

Due to the large sample size, the internal consistency of PSM – items was acceptable (ordinal alpha coefficient 0.68) [39-41]. This variable was analyzed after re-coding four out of five items (0= strongly agree to 4= strongly disagree). These items were inverted for the data collection. PSM was analyzed over time and the decrease in values indicated an increase in self-management. The parameter estimate for time is negative (-0.030), with a p-value <.001, showing a statistically significant improvement in self-management over time (Table 3).

Positive feelings (PF)

The positive feelings variables were also analyzed over time after re-coding three out of nine variables. The lower the value of PF the more participants agreed to the PF statement. The result of the analysis for PF showed a negative parameter (-0.015) for the time slope with p- <.001, indicating that positive feelings increased significantly over time (Table 3).

Participants' evaluation of feedback

Table 5 shows and Figure 1 illustrates that most of the participants who responded to the evening diaries chose one item of evaluation of feedback messages almost every day. In the final days of the intervention, the number of participants who answered the evening diaries decreased. The feedback evaluation that was most often marked was: "The feedback has helped me to stay sufficiently active" (mean =26%) and the feedback message less often marked was: "The feedback has helped me to be aware of my coping strategies" (mean = 6%), see Table 5.

Table 5. Participant's evaluation of feedback messages during 23 days*.

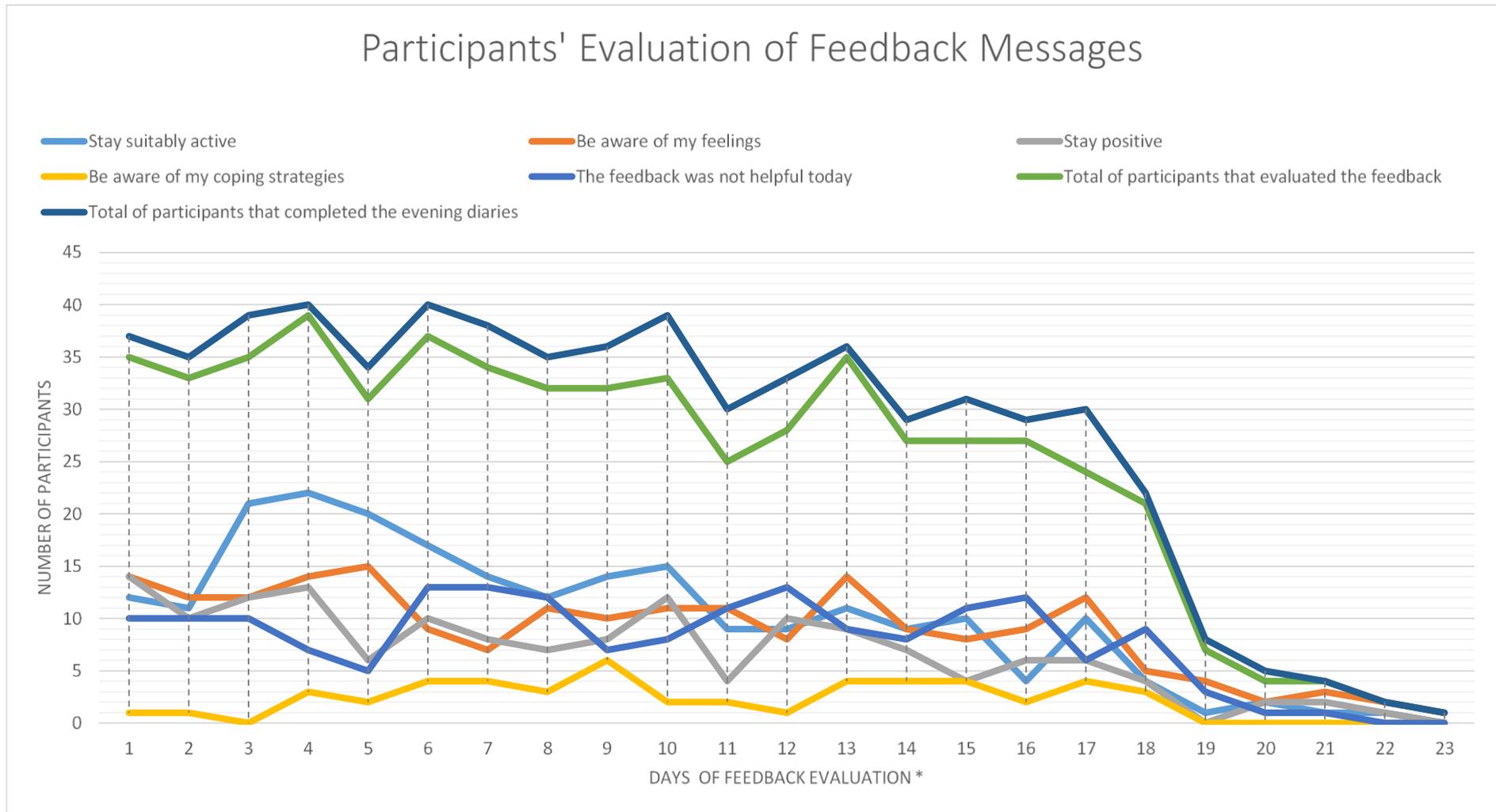
Feedback evaluation	Mean (%)	Std. Deviation	Minimum (n)*	Maximum (n)*
The feedback helped me to stay suitably active	10.00 (26)	6.61	0 (39)	22 (39)
The feedback helped me to be aware of my feelings	8.82 (23)	4.23	1 (39)	15 (39)
The feedback helped me stay positive	6.73 (17)	4.15	0 (39)	14 (39)
The feedback helped to be aware of my coping strategies	2.17 (6)	1.77	0 (39)	6 (39)
The feedback was not helpful today	7.78 (20)	4.28	0 (39)	13 (39)
Completers of the feedback evaluation	24.91 (62)	12.30	1 (40)	39 (40)
Completers of the evening diaries	27.52 (57)	13.41	1 (48)	40 (48)

Legend:

*The participants didn't receive feedback during the first week of the intervention and in the weekends, and these days are therefore not included in the frequencies.

(n)* =Maximum number of possible answers

Figure1. Evaluation of feedback messages by number of participants that answered the evening diary per day



*The participants didn't receive feedback during the first week of the intervention and in the weekends, and these days are therefore not included in the days of feedback evaluation.

DISCUSSION

The analyzed content of the diaries is presented in Table 1 and starts with physical activities. Our results show that both planned and executed activities decreased slightly over time (Table 3). The Figures 2 to 4 illustrate that the level of activity decreased slightly after the first week but remained stable during the next weeks. To interpret these results it is fundamental to know that at the rehabilitation center the patients had an intensive physical activity level [28, 31] and the challenge was to continue to stay active in their daily life after the rehabilitation period. Due to the high level of activities performed at the rehabilitation center, it was expected that the level of activities would decrease at home. The results also show that participants were committed to perform their planned physical activities. This suggests that the objectives of the intervention, i.e. that participants should stay sufficiently active at home was achieved. This is also in line with participants' evaluations of feedback messages, as they most often reported that the feedback has helped them to stay sufficiently active (see Table 5 and Figure 1). One of the main components in chronic pain treatment is to stimulate physical activities and many studies show effective results [3, 4]. To our knowledge, there are no studies on how to stimulate women with CWP to stay suitably physically active after a rehabilitation period. The intervention presented in this paper may represent an alternative. Future studies with an RCT design are necessary to confirm the obtained results. Interestingly, reduction in pain catastrophizing was seen in the previously reported RCT [28], but similar changes in catastrophizing was not seen in the present study (Table 3). Possibly, this is due to differences in the methodology used to assess pain catastrophizing in these two studies (in the RCT study, the Pain Catastrophizing Scale (PCS) containing 13 items was used [42], but in the diaries the pain catastrophizing was assessed using three items from the PCS). However, the lack of a significant reduction in catastrophizing corresponds with a previous mediation analyses, in which data indicated that catastrophizing may not be a central change process in ACT-based treatment [18].

Regarding pain acceptance the results show a statistically significant increase over time (table 3). This result supports the results from the RCT study where the pain acceptance increased after the intervention period and supports the findings from earlier research illustrating that ACT-oriented interventions alter the levels of pain acceptance [24, 43]. It is important to emphasize that a different methodology was also used to evaluate the change in pain acceptance in the RCT compared with the present study. In the RCT the Chronic Pain Acceptance Scale (CPAQ) contained 20 items was used [43]. In the present study only one statement from the CPAQ was applied: "Right now I feel my life is going well, even though I have chronic pain"). Therefore the results are not comparable, but point in the same direction.

Beside physical activity, cognitive behavioral therapy is a major element in the treatment of CWP [3, 4]. In the present study, the ACT processes were applied to stimulate psychological flexibility and achieve self-management. Therefore, questions to stimulate awareness on pain related thoughts (Pain Fear and Avoidance), feelings (Positive Feelings) and behavior support (Pain Self-Management) were included in the diaries (Table 1). The results of these three variables were encouraging, indicating that the psychological condition of participants improved as well as their self-management. Further studies are necessary to replicate these findings.

No correlation between diary contents and feedback messages was found, even though most of the patients stated in their diaries that the feedback was supportive (see Table 5). This result suggests that daily self-monitoring of planned and performed physical activity level, feelings and thoughts related to avoidance, catastrophizing and acceptance is helpful to increase self-management, irrespective of the feedback received. Collinge et al., 2013 also suggested that the effects achieved in their study were not dependent on the feedback given. The authors concluded that by reporting their symptoms electronically, the participants increased their awareness, thus influencing their behavior positively, leading to a symptom reduction [44]. On the other hand, in a review conduct by Baumeister et al., 2014 the authors concluded that guided interventions (with feedback), although small, had better results than unguided interventions (self-monitoring) [45]. The feedback messages in the SMI were individualized to the participants' answers, goals and values. Thereby, the fact that the feedback was individualized may have impacted positively on the results.

Strengths of the study

To our knowledge, this is the first study that analyzes the change processes of a smartphone delivered ACT model intervention by exploring the relationships between participants' daily electronic diaries and therapists' daily personal and individualized written feedback messages. The feedback data were collected daily during four weeks (except on weekends). The diary data were collected daily during five weeks with several variables collected more than once a day. By analyzing these repeated measures, the intention was to enhance the understanding of the change mechanism in this specific intervention. To analyze the effects of randomized controlled studies it is a common practice to apply recognized instruments before and after intervention. When instruments are applied on specific time points, the results can be highly biased by mood, health and social conditions, etc. [46]. By using repeated daily measures, as was done in the present study, it is possible to evaluate the development of measurements over time. Even if these results might as well be influenced by bias, it can be possible to identify trends that hopefully will support the main findings and/or give knowledge to the future development of the intervention.

Limitations

The results of this study should be interpreted with caution, due to a complexity in the intervention, i.e. that the effects may be due to the treatment program, the SMI, or a combination of these [47]. The effects analyzed are interrelated and they are explored in multiple analyses. Also, the analyses of change processes are exploratory and the findings need to be validated by replicating the study in future research, with e.g. other and larger samples as well as other methods for evaluation. For example, this study did not explore if process measures were related to the outcome measures, which should be a focus in future studies, although the previously reported RCT showed improvements in catastrophizing and pain acceptance directly after the intervention [28]. The patients' evaluation of the feedback messages were useful for the therapist, but for research purposes the use of a quantitative rating scale would be more appropriate to strengthen the results.

Practical implications

The data collected in the RCT study from the diaries and feedback messages open up new possibilities of analysis. The main objective of the present study was to understand the change processes of the SMI. We knew from the RCT results that the intervention had effect, but it remained unknown which component of the SMI was responsible for this effect. ACT-principles were underlying the design of the intervention. The results of the present study suggest that the ACT processes, contained in feedback messages, were not connected with changes in the diaries responses. On the other hand, the participants evaluated feedback messages as supportive and the results also suggest that the ACT based diary content had an important role in the achieved effect, indicating that the entire intervention package generated the effect. Development of feasible interventions with a lower level of complexity, increased efficiency and decreased costs are needed. Based on our coding scheme developed in a previous study [32], an automatic generation of feedback messages would be possible. Automatic feedback could be generated from a database and combined with individualized feedback if the diaries indicate this to be required. The intervention could then be developed as an application for smartphones, reducing therapist time and costs. Making such an application available as support for clinical practices and/or in maintenance treatments would help in treating people who do not have easy access to health care institutions. The first step could be to develop and test the concept of automation in a RCT intervention.

CONCLUSION

No support for a relationship between ACT consistent diary content and feedback was found. However, the results from the present study indicate that the hypothesized mechanism of change in the ACT-based

intervention that was seen in the diaries may have contributed to the positive effects achieved. Specifically the processes of committed actions towards own life values may have helped the participants to stay suitably active at home. The diary content may also have contributed to an increased acceptance, self-management, positive feelings and decreased pain fear and avoidance. Although tentative, the results from the present study provide relevant information that will contribute to the further development of smartphone intervention to enhance treatment of CWP.

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Appendix 1. Description of the RCT study

Chronic Widespread Pain (CWP)	
Aim	Investigate the efficacy of a smartphone delivered intervention grounded on ACT following a four-week inpatient chronic pain program at a Norwegian rehabilitation center
Design	This study was a RCT. The participants were randomized in two groups; with or without a follow-up intervention. The intervention started with a personal meeting followed by 5 weeks of 3 daily diaries and 4 weeks of 1 daily feedback (except weekends) via a smartphone. The participants had also access to audio files with mindfulness exercises installed on the smartphone and available in a website with specific information for people with chronic widespread pain.
Diaries	The diaries included 16-24 questions. The questions were chosen to support self-monitoring and awareness of feelings, thoughts related to the symptoms and applied self-management strategies. Most of the questions were answered by choosing predefined alternatives or by scoring on a five-point Likert scale. The diaries also included a comment field giving participants the opportunity to write a short personal message to the therapist.
Feedback	A therapist (nurse and / or psychologist) had immediate access to submitted diaries and used the situational information to formulate personalized feedback grounded on ACT with the aim of stimulating effective self-management of the current situation. The feedback was written in an empathic communication style and included positive reinforcement, information, metaphors, exercises and questions aiming to encourage mindfulness and willingness to engage in meaningful activities despite pain.
Setting and recruitment	A rehabilitation center in Norway. Upon admission to the rehabilitation center all patients in the musculoskeletal pain management program received an information letter about the study, where they were invited to attend an information group meeting. At the meeting a researcher presented the study and those interested in participating and who met the inclusion criteria were given an informed consent form to sign. The rehabilitation program for chronic pain included education and pain management in a cognitive setting, various forms of aerobic exercises, stretching, myofascial pain treatment, relaxation and medication as needed. In the fourth week of the rehabilitation program participants were randomized into an experimental group (follow up intervention) or a control group (website only).
Outcomes	Primary: Pain Catastrophizing Scale (PCS) [1]. Secondary: Pain intensity and fatigue (last couple of days) were assessed on visual analog scales from 0 (no pain/fatigue) to 10 (worst imaginable pain/fatigue), Chronic Pain Acceptance Questionnaire (CPAQ) [2], General Health Questionnaire (GHQ) [3], Chronic Pain Values Inventory (CPVI) [4].
Data collection	The assessment measures were self-administered questionnaires filled out at the rehabilitation center (T1 and T2), at home after the intervention period (T3) and 6 months after discharge from the rehabilitation center (T4). The patients were interviewed in the middle and at the end of intervention.
Study sample	A total of 265 patients were invited and 140 were willing to participate in the study. They were randomized into the two study arms. 5 were excluded after randomization because of being included in another research program. 21 withdrew from the intervention group and 2 from the control group. No differences in demographic or outcome variables were found between completers and non-completers (all p values > 0.1) except for tendency towards higher age in the non-completers group (mean 48.0 years) compared to the completers (mean 43.2 years), p = 0.094. Of those 48 that completed the intervention 47 returned the questionnaires at T3 and 37 at T4. From the control group 37 participants returned the questionnaires at T3 and 40 at T4.
Statistical analysis	Analyses were conducted in SPSS to determine the effects. The effect sizes were calculated using the difference between the group mean divided by the mean standard deviation of both groups. In the intention to treat analysis last observed value was carried forward. If questionnaires included one or two missing items those were replaced with a mean score (rounded to the closest whole number in case of recoding). If two response alternatives were marked the one indicating more health was chosen. If more than two items were missing a total score was not computed.
Results	The response rate to the diary entries during the 4 weeks after discharge ranged from 27.4% to 95.2%, with a mean of 68.5% and a median of 70.2%. After the follow-up period the intervention group reported less catastrophizing (M = 9.2, SD = 5.8) compared to the control group (M = 15.7, SD = 9.1), P = 0.001. Between group effect size (ES) on catastrophizing was large (Cohen's d 0.87, P < 0.001) and remained moderate (0.74, P = 0.003) 6 months after discharge from the inpatient program

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Appendix 2. Examples of variables from feedback codebook chosen for this study with codes' definition and examples of coded text segments of feedback messages

Code	Functions	Examples of coded text segments of feedback
Values (V)	<p>Stimulate patient's reflection on their own values and the values' impact on their life.</p> <p>Help the patient to identify the difference between goals and values.</p> <p>Stimulate awareness of gratitude and enthusiasm regarding feelings for increasing awareness of values.</p>	<p>I think there is a big difference in how much people reflect on their values, actions aimed at achieving these and possible barriers connected to them. But I also believe that by being more aware of those things you can come closer to living according to your life values.</p>
Committed Action (CA)	<p>Encourage the patient to committed behavior related to their own values through reflecting on strategies related to well-planned actions, barrier and follow-up. Stimulate planning of activities in the form of value-oriented goals.</p>	<p>This weekend we will recommend you to think through what you have achieved since you came home from Jeløy. Think through your values and the goals you have set for yourself - and how you move towards them. Remember, each step you take in the right direction is important and can lead you to live the life you want.</p>
Contact with Present Moment (PM)	<p>Stimulate breathing exercises for relaxation and variety in activities.</p> <p>Stimulate attention and awareness of internal and external experiences in the present moment.</p>	<p>As a kind of awareness training can you today be extra conscious of your surroundings? Whatever it is, a conversation with a friend, house cleaning, eating, observing the nature or other things? Try to do only one thing at a time. The challenge is to stay focused on what you are doing and don't let your mind concentrate on something else that can interfere in your exercise. By directing the focus away from what has happened or might happen - you can more easily manage to "live in the present moment".</p>
Cognitive Defusion (CD)	<p>Stimulate awareness of thought processes instead of thought content.</p> <p>Stimulate understanding in thought content as a result of the context in which thoughts are a product of specific (s) situation (s).</p>	<p>I have observed that you usually choose alternatives regarding negative statements in the daily diary (for example: "you are afraid of pain" or "you worry that it will not recede"). This is something to be aware of. It is important to be conscious of how these thoughts might affect your feelings. Then you can choose what to do. Mindfulness training is largely applied to achieve such consciousness.</p>
Acceptance (AC)	<p>Encourage the patient to make active choices to act in accordance with their values, despite the difficult thoughts, emotions and physical sensations that are unpleasant, but which we cannot directly eliminate or reduce.</p>	<p>I see that you are frustrated by the bad weather because you feel that it affects your mood. However you show a positive attitude by hoping for better weather and mood tomorrow. But what can you do today? The weather is like it is, impossible to control. Is there something you can do in spite of it? Could stretching exercises be an alternative?</p>
Behavioral Support (BS)	<p>Support the patient in the change process by recognizing the patient's willingness and efforts to change behavior.</p> <p>Provide confirmation of the patient's coping strategies.</p>	<p>Hi, Here comes the initial feedback and I wish to congratulate you for your efforts during these four weeks of intense treatment at Jeløy. I look forward working with you further and I hope I can support you doing what you evaluate as good for you.</p>
Advise (Ad)	<p>Give specific and constructive advice for appropriate behavior or to specific situations.</p>	<p>It is challenging to come back to your home. So be patient! Regards Ann</p>
Empathic Statements (ES)	<p>Recognize the patient's experiences and feelings, showing empathy, understanding and respect.</p>	<p>You wrote that you are trying to think positively but that this is not easy when you have headaches and are tired. I understand you very well!</p>

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