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Citation for the original published paper (version of record):

Emilson, C., Demmelmaier, I., Bergman, S., Lindberg, P., Denison, E. et al. (2017)
A 10-year follow-up of tailored behavioural treatment and exercise-based physiotherapy for
persistent musculoskeletal pain.
Clinical Rehabilitation, 31(2): 186-196
<https://doi.org/10.1177/0269215516639356>

Access to the published version may require subscription.

N.B. When citing this work, cite the original published paper.

Permanent link to this version:

<http://urn.kb.se/resolve?urn=urn:nbn:se:mdh:diva-34888>

A 10-year follow-up of tailored behavioural treatment and exercise-based physiotherapy for persistent musculoskeletal pain

Christina Emilson¹, Ingrid Demmelmaier¹, Stefan Bergman², Per Lindberg³, Eva Denison⁴, Pernilla Åsenlöf¹

1. Department of Neuroscience, Uppsala University, Uppsala, Sweden
2. Research and Development Center Spenshult, Halmstad, Sweden
3. Department of Psychology, Uppsala University, Uppsala, Sweden. Department of Public Health, and Community medicine, The Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden.
4. School of Health, Care and Social Welfare, Mälardalen University, Västerås, Sweden

Correspondence

Christina Emilson
Department of Neuroscience
Uppsala University
Box 5932
S-751 24 Uppsala
Sweden
E-mail: christina.emilson@neuro.uu.se
Telephone number: +46 18 471 4779
Fax number: +46 18 511 540

Key words

Chronic pain, Behavioural medicine, Primary care, Physical exercise, Long-term compliance

Funding sources

The study received financial support from the Swedish Rheumatism Association, Uppsala County Council, and Caring Sciences Funding at the Faculty of Medicine, Uppsala University.

Conflicts of interest

None declared.

The manuscript contains original unpublished work and is not being submitted for publication elsewhere. All authors meet the criteria for authorship, and all authors discussed the results and commented on the manuscript. The study was approved by the regional ethical review board in Uppsala.

Abstract

Objective: To study the long-term outcomes of two interventions targeting patients with sub-acute and persistent pain in a primary care physiotherapy setting.

Design: A 10-year follow-up of a two-armed randomised controlled trial, initially including 97 participants.

Interventions: Tailored behavioural medicine treatment, applied in a physiotherapy context (experimental condition), and exercise-based physiotherapy (control condition).

Main measures: Pain-related disability was the primary outcome. The maximum pain intensity, pain control, fear of movement, sickness-related absence (register data) and perceived benefit and confidence in coping with future pain problems were the secondary outcomes.

Results: Forty-three (44%) participants responded to the follow-up survey, 20 in the tailored behavioural medicine treatment group and 23 in the exercise-based physiotherapy group. The groups did not differ in terms of the change in the scores for the primary outcome ($p=0.17$) of pain-related disability between the experimental group (*median*: 2.5, *Q1-Q3*: 2.5-14.25), and the control group (*median*: 0, *Q1-Q3*: 5-6). Further, there were also no significant differences found for the secondary outcomes except for sickness-related absence, where the exercise-based physiotherapy group had more days of sickness-related absence three months before treatment ($p=0.02$), and at the 10-year follow-up ($p=0.03$).

Discussion: The beneficial effects favouring tailored behavioural medicine treatment that observed post-treatment and at the two-year follow-up were not maintained 10 years after treatment.

Introduction

In a randomised controlled trial conducted 10 years ago, the effects of tailored behavioural medicine treatment that included a graded activity format were compared with the effects of exercise-based physiotherapy in patients with musculoskeletal pain treated in a primary care physiotherapy setting (1). Behavioural medicine treatments, i.e., the application of principles and procedures emanating from operant learning theory (2, 3), and graded activity are methods used in pain rehabilitation to achieve a general goal of returning to an active everyday life regardless of the pain level (4). The tailored behavioural medicine had a greater impact on pain-related disability than exercise-based physiotherapy, and the results were maintained over two years post-treatment (5). Maintenance of reduced pain-related disability over an even longer time in this population is still unknown, and therefore it is important to determine whether the initial benefits are sustained or not, 10 years after the intervention.

Long-term follow-ups extending more than one year are rare in the pain management literature, but sustained positive outcomes have been reported in favour of behavioural medicine treatments after five years regarding pain and pain-related disability (6), and after 10 years regarding sickness-absence (7). Studies of multidisciplinary rehabilitation programs for musculoskeletal pain in primary care settings have reported lower health care utilisation and use of pain medication at a three-year follow-up (8), improved health-related quality of life and increased return-to-work at a five-year follow-up (9).

Long-term follow-ups of pain rehabilitation programs at a pain clinic, indicate an improved return-to- work rate (10) and beneficial effects on pain and physical function (11). However, specific behavioural medicine treatment components were not included or described in most of the studies.

The aim of this study was to investigate whether the formerly reported beneficial short-term effects were sustained 10 years after the completion of treatment. The primary outcome was pain-related disability. The maximum pain intensity level, pain control, fear of movement/ (re)injury, sickness-related absence and self-reported benefit were evaluated as secondary outcomes.

Methods

The original study

A brief summary of the methods employed in the original study is provided below. For an extended description, please refer to the original publication (1). The study was a randomized controlled trial that included two active treatments: 1) a tailored behavioural medicine treatment protocol and 2) an exercise-based physiotherapy protocol. No manual treatments were allowed in either of the conditions. The physiotherapists were trained to deliver treatments in accordance with these protocols before the start of the study. One unique feature of the behavioural medicine treatment was the tailoring of the contents of treatment according to individual behavioural goals

and functional behavioural analyses (12). The exercise-based physiotherapy protocol was based on the best available evidence regarding physical exercise in long-term pain management. The intervention lasted for three months and consisted of eight to 10 sessions (*median*: nine) in the behavioural medicine treatment group, and nine to 12 sessions (*median*: 10) in the physical exercise-based group. Data and results at post-treatment and at the two-year follow-up have previously been reported (1, 5).

Inclusion criteria

The participants were recruited from three physiotherapy units in the primary care settings from 2003 to 2004. The eligible patients were between 18 and 65 years of age and consulted primary care due to sub-acute, recurrent, or persistent musculoskeletal pain, mainly from the low back, shoulders and neck. A total of 122 participants were recruited, 97 of whom completed the intervention (figure 1). Participants were randomised into blocks of ten per unit using a random digit table. The participants and physiotherapists at the primary care units were blinded to the allocation sequences.

Insert figure 1

The 10-year follow-up

Both the original and follow-up studies were approved by the regional ethics review board in Uppsala, Sweden (d.nr: 01-34899 for the original study and d.nr: 2012/ 512 for the follow-up study).

The participants were traced through the personal data collected during the original study (figure 1). The contact information was updated and checked against the Swedish population register. Two of the participants had died, and contact information for another three of the participants could not be found in the register, leaving 92 participants eligible for follow-up. Informed consent was obtained from each participant concurrent with data collection at the 10-year follow-up. For those who consented to participate, registry data on sick leave were collected from the Swedish Social Insurance Agency Register. For the present 10-year follow-up, data were collected either by regular mail or by a web survey according to the participants' preferences. Reminders were sent out after two and six weeks.

Outcome measures

Pain-related disability

The Pain Disability Index (PDI) is a seven-item questionnaire used to measure self-reported disability and the impact of pain on activities of daily living and social role functioning (13). The item response format ranges from 0 = no disability to 10 =

maximum disability. The total summed score thus ranges between 0 and 70. The reliability and validity of the Pain Disability Index have been shown to be satisfactory for patients with long-term pain (14), and it discriminates outpatient samples from in-patient samples (15). The responsiveness for change was good in patients with low back pain (16). A cut-off score of 4 has been reported to reflect recovery (17). The Swedish version of the Pain Disability Index was used in the present study (18).

Pain intensity and pain control

The maximum pain intensity experienced during the past two weeks was scored on a numerical rating scale ranging from 0 = no pain to 10 = worst pain imaginable (19). A score of five or higher has been associated with disability (20).

The perceived pain control with respect to the participants' strategies to handle pain during an average day was scored on a numerical rating scale from 0 = no control to 10 = total control (21). The predictive validity of the numerical rating scale for pain measurement is good, and has been reported to be sensitive to change (22).

Fear of movement/(re)injury

The patients' fear of movement/(re)injury was measured with The Tampa Scale for Kinesiophobia (TSK), which consists of 17 items (18, 23). Each item is rated on a scale ranging from 1 = strongly disagree to 4 = strongly agree. The total score ranges between

17 and 68. Higher total score indicates more fear. The Swedish version (TSK-SV) used in this study is valid and reliable in patients with long-term low back pain (24).

Sickness-related absence

Data on sickness-absence periods were gathered from the Swedish Social Insurance Agency Register during the whole period from three months prior to baseline to the 10-year follow-up. The register includes data on sickness-related compensation periods (i.e., days of sick leave and disability pension) exceeding 14 days, and different degrees of compensation from 25% to 100% of the full-time compensation is also available.

Self-reported benefit

Self-reported benefit from the intervention and confidence in solving future problems were measured by two study-specific ordered-category items. The first question was: *“To what degree have you had benefits from what you learned from treatment?”* A four-point item ranging from 1 = “no benefit” to 4 = “very large benefit” was used. The second question was: *“How confident are you that you can cope with future problem situations?”* A five-point item ranging from 1 = “very confident” to 5 = “very unconfident”.

Data management

Immediate post-treatment data, i.e., approximately three months after the start of treatment, and 10-year follow-up outcome data were used in this study with the

exception of sickness-related absences, which covered the entire study period from three months prior to baseline to the 10-year follow-up.

The change scores were calculated for the differences between the scores from each outcome measure at post-treatment and at 10-year follow-up regarding pain-related disability, maximum pain, pain control and fear of movement. A median was calculated for the change score on each variable. In cases where there were missing data in the questionnaires, the items were substituted with the mean of each individual's total score. Missing data were found for a total of three items from three different individuals in the Tampa Scale for Kinesiophobia.

Regarding the total days of sickness-related absence, three periods were analysed: from three months prior to baseline until baseline, from baseline until post-treatment, and from post-treatment until the 10-year follow-up.

The degree of sickness-related absence from the registered data varied from 25 to 100 per cent of compensation. In the calculation of sickness-related absences, the data were added to account for the total number of full days of sickness-related absence (100%) during the entire period from three months prior to the baseline until 10 years post-treatment, regardless of the type and degree of compensation (i.e., sick leave and disability pension). The data were dichotomised into two categories (i.e., absence/no absence) for the analysis of sickness-related absence.

Statistical methods

The data were analysed by non-parametric statistical methods due to the mainly ordinal data values and the small sample size. Per protocol analyses were applied. No intention-to-treat analyses were performed due to the extended length of time that had passed since the previous data collection.

The demographic variables (gender, marital status, education, and working status) for the two groups were visually inspected and compared. Differences between those who responded and those who did not at the 10-year follow-up were assessed using the same inspection and complementary chi-square tests for the demographic data and Mann-Whitney *U*-tests for the outcome variables.

The between-group analyses were based on the changes in the scores from the post-treatment evaluation to the 10-year follow-up and were performed using Mann-Whitney *U*-tests.

Analyses utilizing a binominal distribution of the presence of sickness-related absence (i.e., absence/no absence) were performed using Fisher's exact test for the four assessment points (three months prior to baseline, baseline, post-treatment, and 10-year follow-up). The differences in the total days of sickness-related absence between the two groups for the three periods were analysed with Mann-Whitney *U*-tests. The analyses were performed both including and excluding outliers ($n = 5$).

Follow-up data from the questions: *“To what degree have you had benefits from what you learned from treatment?”* and *“How confident are you that you can cope with future problem situations?”* were analysed with Fischer’s exact test.

All analyses were performed using the IBM Statistical Package for the Social Sciences (SPSS) version 21.0 software program. An alpha level of 0.05 or below was regarded as statistically significant.

Results

Data from a total of 43(44%) participants of the original group were collected at the 10-year follow-up (table 1). Twenty and 23 of these participants originally belonged to the tailored behavioural medicine and exercise-based physiotherapy groups, respectively. Thirty-three (77%) participants were women, while 10 (23%) were men. Regarding employment, 32 (74.4%) of the participants worked outside their home, seven (16.3%) were retired, and two (4.7%) were on sick leave. One (2.3%) participant was on maternity leave, whereas two (4.7%) reported no employment. High school or university education was reported by 35 (81.4%) of the participants, and 32 (74.4%) were married or cohabitating. The treatment groups had a similar distribution in demographic variables.

Attrition

The follow-up questionnaire was sent out to the 92 of the former 97 participants who completed the intervention, and 49 (53%) of these participants did not respond. Two of the former participants had died and three of them could not be identified. There were no evident differences in pain-related disability, maximum pain intensity, pain control, or fear of movement immediately after treatment, i.e., three months from start of treatment, for those who completed the follow-up and those who did not (table 1). Neither did they seem to differ in any of the demographic variables at baseline (table 1).

Insert table 1

Primary outcome (pain-related disability)

No significant differences in the change in the pain-related disability scores from immediately post-treatment to 10 years after treatment were found (table 2). Thirteen participants (30%) reported a Pain Disability Index score of four or lower, which indicated low levels of pain-related disability. The distribution of these participants was equal in both of the groups.

Secondary outcomes

A significant difference in the change scores from immediately post-treatment to 10 years after treatment was seen for the maximum pain intensity. The tailored behavioural medicine group reported increased levels of pain, whereas the exercise-based physical group reported decreased levels (table 2). In total, 24 (56%) of the participants in the

10-year follow-up reported a score of 5 or higher for the maximum pain intensity. The two groups did not differ significantly in terms of the pain control or fear of movement (table 2).

Insert table 2

Sickness-related absence

Regarding the presence of sickness-related absence at three months prior to baseline, at baseline, post-treatment, and at the 10-year follow-up, no between-group differences were found except for three months prior to baseline (Table 3).

In terms of the total days of sickness-related absence (exceeding 14 days), significant differences were found between the tailored behavioural medicine treatment and the exercise-based physiotherapy both three months before intervention and at the 10-year follow-up (table 3).

Insert table 3

Self-reported benefit

Regarding the question about “*perceived benefit of the former treatment*”, no significant differences were found between the groups ($p = 0.95$). Similarly, there were no significant differences regarding the question about “*confidence in coping with future*

problem situations” between the groups ($p = 0.63$). However, the response pattern differed between the groups for both questions (table 4).

Discussion

The present results demonstrated that the tailored behavioural medicine treatment group and the exercise-based physiotherapy group did not differ in their self-reported pain-related disability, pain control, fear of movement and sickness-related absence 10 years after treatment. Hence, the beneficial effects in favour of the tailored behavioural medicine treatment group observed post-treatment and at the two-year follow-up no longer existed at ten years post-treatment.

A significant difference in the change in the scores for the maximum pain intensity was noted, which can be explained by the increased levels of pain in the behavioural medicine group and the decreased levels in the exercise-based physical therapy group. This means that the differences reported in the previous studies had levelled out.

The rationale behind the treatments included in the original study was to target pain-related disability, and not pain intensity. More than half of the participants evaluated in the 10-year follow-up still experienced moderate to severe pain (i.e., ≥ 5 in the numerical rating scale). At the same time, the median levels of pain-related disability and sickness-

related absence were low (table 3). Other studies indicate that pain intensity ratings exceeding five on a 10-point rating scale imply more severe pain-related disability (20), which was not necessarily the case in the present study. Previous studies state that a score of 0-4 reflects recovery on the Pain Disability Index, whereas 5- 21 indicates moderate disability and 22 or higher indicates high level of disability (17, 25).

The total number of sickness-related days of absence was lower in the tailored behavioural medicine group compared with the exercise-based physical therapy group, during the period from the post-treatment evaluation to the 10-year follow-up. However, the rate of sickness-related absence was also lower in the tailored behavioural medicine group compared with the exercise-based physical therapy group three months prior to baseline. A few participants in the exercise-based physical therapy group were absent due to sickness during the entire period, which is a plausible explanation for the detected difference. A limitation regarding the data on sickness-related absence is that information about short periods of sick leave (i.e., < 14 days) is not reported to the Swedish Insurance Agency registry. We therefore do not have access to information about short-term sickness-related absences.

One goal of the tailored behavioural medicine treatment was to guide participants in the management of important and common everyday life activities and situations, while controlling the influence of pain. At the 10-year follow-up, 66% of the participants in the tailored behavioural medicine group rated their confidence in solving future problem

situations high or very high, compared to 35% in the exercise-based physical therapy group. The tailored behavioural medicine group was also explicitly trained to manage demanding future situations. Participants who had successfully incorporated such strategies into their everyday life may have maintained their confidence to cope with particularly challenging situations despite their current pain. However, no significant differences were found between the groups in terms of their confidence in coping with challenging situations in the future.

Long-term follow-ups of rehabilitation interventions are rare and difficult to perform, making this study unique in its scope and aim. In particular, when studying the effects of treatments aimed at the adoption and maintenance of behaviour changes, it is of great interest to know whether the effects on target behaviours persist in the long run.

Nevertheless, our study raises important issues regarding the challenges of long-term follow-ups of randomized controlled trials and whether they provide valid data. The attrition rate in our study was 56%, which is slightly higher than that in one of the few long-term follow-up studies in this field, which reported an attrition rate of 40% after five years (6). The criteria for acceptable loss to follow-up vary between 20 and 50% in the literature (26), while the criterion for differentiating between high- and low-quality randomized controlled trials is usually set at <20% (Oxford CEBM, SBU). Given the long time span, a response rate of nearly 50% could be regarded as good enough provided that it did not introduce any serious selection biases. In support of this, we did

not detect any obvious differences between groups with respect to drop-outs, the participant characteristics, or the levels of different outcomes measures.

Another limitation was that our study was not sufficiently powered to detect meaningful differences after 10 years. However, this is only of interest if there are relevant differences to detect. Inspecting our data with that question in mind, we still conclude that the effects of the interventions have converged and that the groups did not differ in any statistically significant or clinically relevant aspect after 10 years (16, 27). A plausible limitation is the external validity considering the attrition rate. Thus, we found no clear indication that we would have come to other conclusions regarding the generalisation of the study outcomes for similar samples of adults treated for their persistent pain in the primary care setting if the attrition rate had been lower. However, due to the small sample size, the results should be interpreted and transferred with some caution. We also do not have any data on the respondents or the non-respondents regarding co-morbidities, important life events, or health care utilization, including the amount and content of pain treatments, over the ensuing 10 years.

Based on our experiences from the current study and from the literature (26), our conviction is that long-term follow-ups contribute with valuable knowledge. We suggest that the criteria used for long-term follow-ups, i.e., that the CONSORT statements are reviewed and further developed. In order to stimulate and facilitate the reports of long-term outcomes such developed criteria should be applied despite threats

to internal and external validity. For instance, attrition may not be such a serious problem if data are missing at random or missing completely at random compared to when not missing at random (28) in such case also a small attrition rate can be hazardous.

Clinical Message

- Ten years after treatment, there were no significant differences in the outcomes between those who were exposed to behavioural medicine treatment and those who received exercise-based physiotherapy

Conflict of Interest Statement

The authors declare that they have no conflicts of interest.

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Table 1 Comparisons of demographic variables at baseline and outcome variables immediately post-treatment* for those who completed the 10-year follow-up, and those who did not.

	Completed follow-up <i>n</i> =43 (44.3%)	Did not complete follow-up <i>n</i> =54 (56.7%)
Outcome variable	<i>Mdn</i> (Q1-Q3)	<i>Mdn</i> (Q1-Q3)
Disability	10.0 (3.0-23.0)	10.0 (4.5-25.0)
Pain max	5.0 (3.0-8.0)	5.0 (3.0-8.0)
Pain control	7.0 (6.0-9.0)	6.5 (5.0-8.0)
Fear of movement (TSK)	26.0 (23.0-32.0)	27.0 (23.5-34.3)
Demographic variable		
Mean age (<i>SD</i>)	44.4 (11.7)	41.1 (11.4)
Gender = <i>n</i>		
Male	10	12
Female	33	42
Marital status = <i>n</i>		
Married/ cohabitans	33	40
Single	9	13
Living with parents	1	1
Education = <i>n</i>		
Elementary school	10	17
High school	14	21
University	19	15
Working status = <i>n</i>		
Full-time	20	29
Part-time	14	10
Other**	9	15
Ethnicity = <i>n</i>		
Swedish	39	48
Other	4	3
Pain location = <i>n</i>		
Low back	12	13
Neck	2	1
Shoulder, arm. Hand	5	5
Hip, knee, foot	1	1
Other	3	2
Two or more sites	20	32

Mdn= median

Q= quartile

SD= standard deviation

Three months after treatment start

Disability: Pain Disability Index, PDI (0-70), low scores indicate low disability

Maximum pain intensity and Pain control: Numerical rating scale NRS (0-10), low scores indicate low pain intensity/ pain control.

Fear of movement/ (re)injury: The Tampa Scale of Kinesiophobia, TSK (17-68), low scores indicate low fear.

** Unemployed, student, maternity leave or sick-leave

Table 2 Differences in change scores between group- analyses of pain-related disability, maximum pain intensity, pain control and fear of movement/ (re)injury, immediately at post-treatment and the 10-year follow-up.

Outcome Measurement	Post-treatment <i>Mdn (Q1-Q3)</i>	10-year follow-up <i>Mdn (Q1-Q3)</i>	Change score <i>Mdn (Q1-Q3)</i>	Between-group <i>p</i>
<i>n</i> =43				
Disability (PDI)				
TBT	4.5 (0.3-12.0)	10.0 (2-18.5)	2.5 (-2.5–14.25)	0.17
EBT	15.0 (10.0-35.0)	15.0 (7.0-29.0)	0.0 (-5.0-6.0)	
Pain max				
TBT	3.0 (2-5.75.0)	6.0 (2.3-8.0)	1.0 (0.0-5.0)	0.03
EBT	8.0 (4.0-9.0)	6.0 (2.0-9.0)	0.0 (-3.0-2.25)	
Pain control				
TBT	8.0 (6.5-10.0)	7.5 (5.0-8.8)	0.0 (-4.0-2.0)	0.49
EBT	7.0 (5.0-8.0)	7.0 (4.0-8.0)	0.0 (-2.3-2.0)	
Fear of movement (TSK)				
TBT	25.0 (22.0-31.8)	28.5(23.0-33.0)	2.3 (-1.8–8.8)	0.25
EBT	28.0 (23.0-35.0)	29.0(25.0-37.0)	2.0 (-4.0-7.0)	

Mdn= median

Q= quartile

TBT= Tailored behavioral medicine treatment.

EBT= Exercise based physiotherapy.

Disability: Pain Disability Index, PDI (0-70), low scores indicate low disability

Maximum pain intensity and Pain control: Numerical rating scale, NRS (0-10), low scores indicate low pain intensity/ pain control.

Fear of movement/ (re)injury: The Tampa Scale of Kinesiophobia, TSK (17-68), low scores indicate low fear

Table 3 Differences in sickness-absence from three months prior to baseline to 10 years follow-up between the tailored behavioural medicine treatment group, and the exercise-based physiotherapy group.

Presence of sickness-absence yes/ no <i>n</i> = participants	Tailored behavioural medicine treatment <i>n</i> = 20	Exercise-based physical therapy <i>n</i> =23	Difference Chi-2 test <i>p</i> -value
<i>3 months prior to baseline</i>	1/ 19	7/ 16	0.05
<i>Baseline</i>	2/ 18	9/ 14	0.10
<i>Post-treatment</i>	3/ 17	7/ 16	0.29
<i>10-year follow-up</i>	2/ 18	4/ 19	0.67
Sickness-absence <i>n</i> = days	Tailored behavioural medicine treatment <i>n</i> = 20 <i>Mdn (Q1-Q3)</i>	Exercise-based physical therapy <i>n</i> = 23 <i>Mdn (Q1-Q3)</i>	Difference Mann-Whitney <i>U</i> -test <i>p</i> -value
<i>Period 1</i>	0 (0.25-1)	1 (1-1)	0.02
<i>Period 2</i>	0 (0)	0 (0-51)	0.08
<i>Period 3</i>	0 (0-64)	151 (0-1240)	0.03

Mdn= median

Q= quartile

Period 1: Three months prior baseline to baseline

Period 2: Baseline to post-treatment

Period 3: Post-treatment to 10 year follow-up

Table 4 Self-reported benefit and confidence in coping in the tailored behavioural medicine treatment group, and the exercise-based physiotherapy group.

Self-reported benefit	Tailored behavioural medicine treatment n= 20	Exercise-based physical therapy n= 23
<i>Perceived benefit of the former treatment (=n)</i>		
1. No benefit	5	5
2. Little benefit	6	9
3. Large benefit	6	6
4. Very large benefit	3	3
Do not know/ remember	0	0
<i>Confidence in coping with future problem (=n)</i>		
1. Very confident	5	3
2. Confident	8	5
3. Somewhat unconfident	4	8
4. Unconfident	1	7
5. Very unconfident	2	0

Fig. 1. CONSORT diagram over participant flow through recruitment, baseline assessment, randomisation, post-treatment, 2 and 10-year follow-up.