

RESEARCH ARTICLE

The effect of psychomotor physical therapy on health-related quality of life, pain, coping, self-esteem, and social support

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Abstract

Background: Norwegian psychomotor physiotherapy (NPMP) is commonly applied for patients with long-lasting pain and psychological symptoms. The approach is based on a bio-psychosocial model of health and might have benefits to physical, psychological, and physical domains of health-related quality of life (HRQOL). No previous randomized controlled clinical trials have been performed to examine the effectiveness of NPMP as individual treatment. The aim was therefore to assess the effect of a 6-month intervention of NPMP on HRQOL and on pain, coping, social support, and self-esteem.

Methods: The study was a pragmatic randomized controlled trial comparing an intervention group with a control group. Participants were recruited from 36 physiotherapists specialized in NPMP, working in private practice. The intervention group received NPMP once weekly for 6 months, whereas the control group received no intervention. Measurements were performed at baseline and after 6 months. A total of 105 participants were included. HRQOL was measured by the 36-item Short Form Health Survey, SF-36. To examine the effect of the intervention, independent sample *t* tests were performed with the “difference in mean values,” delta ($=\Delta$, posttest result – baseline result).

Results: Significant differences between the two groups were observed in six of the eight SF-36 domains: Physical Functioning, Bodily Pain, General Health, Mental Health, Social Functioning, and Vitality. Effect size ranged from 0.9 for Vitality to 0.3 for Role Physical and Role Emotional. Furthermore, there was a significant difference between groups regarding pain and self-esteem in favour of the intervention group. The Cohen's *d* effect sizes of the different dimensions of HRQOL ranged from 0.3 to 0.9 with a median of 0.6.

Conclusion: The results of this study demonstrate that 6-month intervention of NPMP increased HRQOL and self-esteem as well as reduced pain.

KEYWORDS

health-related quality of life, psychomotor, quantitative research, RCT

This trial is registered in <http://clinicaltrials.gov> with ref. NCT02282007.

1 | INTRODUCTION

Improved health-related quality of life (HRQOL) is probably the most desirable outcome of all health care (Bergland & Narum, 2007a; Farquhar, 1995; Guyatt, Jaeschke, Feeny, & Patrick, 1996) and has

become an increasingly important focus of theory, research, and practice in rehabilitation (Fabian, 1991; Renwick, Friefeld, Renwick, Brown, & Nagler, 1996; Zhang, 2017). According to Berzon, Mauskopf, Simeon, and Spilker (1996), HRQOL refers to patients' appraisal of and satisfaction with their current level of health and functioning as compared with what they perceive to be possible or ideal. The use of HRQOL measures reflects the growing appreciation of the importance of patients' reports on how satisfied they are with their treatment, in addition to the traditional focus on disease outcomes (Bergland & Narum, 2007b; Deyo, 1991; Gill & Feinstein, 1994; Guyatt et al., 1996; McKeivitt, Redfern, La-Placa, & Wolfe, 2003; Muldoon, Barger, Flory, & Manuck, 1998).

Norwegian psychomotor physical therapy (NPMP) belongs to the realm of so-called "Body and Mind" or "Body Awareness" therapies (Kvåle & Ljunggren, 2007). The main body awareness therapies used by in physiotherapists are NPMP, basic body awareness therapy (BBAT), Mensendieck system physical therapy, relaxation, and meditation programmes (Kvåle & Ljunggren, 2007). Physiotherapy has become an important contributor to those applying for help within the arena of mental health and psychosomatics (Gyllensten, 2001; Mattsson, 1998; Roxendal, 1985). BBAT has shown to be effective in people suffering from chronic pain and psychosomatic illnesses (Catalan-Matamoros, Helvik-Skjaerven, Labajos-Manzanares, Martínez-de-Salazar-Arboles, & Sánchez-Guerrero, 2011; Danielsson, Papoulias, Petersson, Carlsson, & Waern, 2014; Mattsson, Wikman, Dahlgren, & Mattsson, 2000; Olsen & Skjaerven, 2016; Seferiadis, Ohlin, Billhult, & Gunnarsson, 2016). NPMP is process oriented, and the aim of treatment is to facilitate change of the affected functions through training, massage, and therapeutic reflection. The training consists of body awareness through grounding exercises, as well as relaxation training (Øien, Iversen, & Stensland, 2007; Thornquist & Bunkan, 1991). The approach is based on the theory that bodies react to physical, emotional, and social strain that may influence the whole body and can affect respiration, muscular tension, posture, balance, movements, flexibility, and body awareness (Ekerholt & Bergland, 2004, 2006, 2008; Øien et al., 2007). In line with NPMP, BBAT is a health-oriented and person-centred approach with a focus on the patient's resources (Antonovsky, 1987; Roxendal, 1985; Skjaerven, 2002) from a multidimensional approach; it is based on four perspectives: the biomechanical, physiological, bio-psychosocial, and existential (Dropsy, 1998; Skjaerven, 2002; Skjaerven, Kristoffersen, & Gard, 2008). These aspects mutually and simultaneously influence each other. Like NPMP, BBAT is a movement awareness training approach in physiotherapy aiming to promote movement quality in daily life through self-exploration and self-experience with a goal of learning new movement habits (Olsen & Skjaerven, 2016; Skjaerven et al., 2008). BBAT has shown to be effective in people suffering from chronic pain and psychosomatic illnesses (Catalan-Matamoros et al., 2011; Danielsson et al., 2014; Mattsson et al., 2000; Olsen & Skjaerven, 2016; Seferiadis et al., 2016). Different authors have described the importance of awareness for BBAT (Gard, 2005; Gyllensten, Skär, Miller, & Gard, 2010; Skjaerven et al., 2008). Awareness can be defined as an attentive, relaxed, and alert presence, not analogous to concentration (Skjaerven, Kristoffersen, & Gard, 2010). Being aware means continually monitoring internal and external

environments (Kvåle & Ljunggren, 2007; Quezada Berumen, González Ramírez, Cebolla i Martí, & Soler Ribaudi, 2014; Skjaerven et al., 2010).

Like BBAT, NPMP is applied to patients with widespread and long-lasting musculoskeletal pain and/or psychosomatic disorders. These elements are addressed when grasping the patient's history of complaints, as well as during body examination and treatment (Thornquist & Bunkan, 1991). Most of the patients referred to NPMP have subjective health complaints defined as complaints without objective findings (Ihlebak, Eriksen, & Ursin, 2002). General practitioners refer patients to NPMP for health complaints such as fibromyalgia, anxiety or depression, and widespread pain, which is often presented as more or less diffuse complaints (Kamps & Arnesen, 2004). The majority of patients are women, and their health problems have often lasted over several years (Aabakken, Aabakken, Øfsti, Schröder, & Wilhelmsen, 1991; Breivte, Hynninen, & Kvåle, 2008). Studies on characteristics of patients referred to NPMP demonstrate a high incidence of co-morbid emotional issues (Kvåle, Ellertsen, & Skouen, 2001; Malmgren-Olsson & Armelius, 2003). Most of the referred patients report symptoms such as anxiety, sadness, and difficulty sleeping (Malmgren-Olsson & Armelius, 2001). Breivte et al. (2008) suggest that psychomotor physiotherapy as a treatment approach is often initiated as a "last resort" for "difficult" patients or when other interventions have not been effective.

In NPMP, pain is seen as a complex bio-psychosocial phenomenon (Ekerholt & Bergland, 2004). Pain was defined by the International Association for the Study of Pain (2017) as "An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage." The body is emphasized as a source of information and a mediator of previous experiences, trauma, stress, personality and emotions, and the patient is invited to a collaborative exploration of what bodily symptoms, such as pain and muscular tension, are trying to convey (Øien, Råheim, Iversen, & Steihaug, 2009).

An important focus of the NPMP approach is the patients' coping behaviours, self-esteem, and social support. Coping theories suggest that supportive actions taken by the person himself and by social support can mediate between the perceived threat of the stressor and stress-related outcomes (Bandura, 1997; Glanz & Schwartz, 2008; Lazarus, 1993; Wenzel, Glanz, & Lerman, 2002). Coping is a psychological construct that captures a person's perceptions about himself as an active agent in his environment (Rothbaum, Weisz, & Snyder, 1982). When there is an imbalance between perceived demands and perceived resources, stress may develop (Lazarus, 1993). A person's coping resources influence how stressful life experiences are perceived, and this is related to patterns of thinking and emotional reactions (Lazarus, 1993; Pearlin & Schooler, 1978). Glanz and Schwartz (2008) present two strategies for coping; there is problem-focused coping, which comprises strategies that are directed at changing the stressful situation and include action, problem solving, and information seeking. By contrast, emotion-focused coping efforts are directed at changing the way one thinks or feels about a stressful situation, and these strategies include the seeking of social support, venting of feelings, avoidance, and denial. When stressors are changeable, problem-focused strategies will be most adaptive, but if a stressor is unchangeable, emotion-focused coping strategies are most adaptive

(Glanz & Schwartz, 2008). Sasaki and Yamasaki's conceptualization of coping (Horiuchi, Tsuda, Aoki, Yoneda, & Sawaguchi, 2018) is classified into four categories: emotional expression (e.g., negative feelings and thoughts), emotional support seeking (e.g., approaching loved ones to request encouragement), cognitive reinterpretation (e.g., reframing a problem positively), and problem solving (e.g., working to solve a problem). In general, coping researchers agree that the study of coping is fundamental to an understanding of how stress affects people, for better and for worse. At the same time, however, there seems to be little agreement on how to conceptualize or measure the central construct.

Important aspects of coping processes can be linked to self and self-esteem that can reflect a person's degree of confidence in self-management of challenges and self-control (Pearlin & Pioli, 2003). Adequate and sufficient self-esteem and social support are important resources in coping with negative life experiences (Pearlin & Schooler, 1978; Rothbaum et al., 1982). Self-esteem is defined as the personal judgement of worth, or how much an individual accepts himself or herself (Ben-Zur, 2002; Fox, 2000; Rogers, 1961; Rosenberg, 1965a, 1965b). The concept touches the individual experience of positive or negative emotions related to self, including the physical body (Ben-Zur, 2002; Rosenberg, 1965b). Social support is information that leads a person to believe that she is cared for and loved, valued, and a member of a network of mutual obligations (Cobb, 1976). Health status (including physical and mental health, and disability restrictions) determines whether a person is capable of performing social activities and performing social activities are of importance for social support (Curvers, Pavlova, Hajema, Groot, & Angeli, 2018). For many years, researchers have been collecting evidence that social ties influence personal health. Personal social networks can influence what we do, how we feel, or the help we can get to cope with life events that have direct and indirect implications for our health and well-being (Berkman & Glass, 2000; Thoits, 2011; White, Philogene, Fine, & Sinha, 2009). Thus, because social support is positively related to health status (White et al., 2009), interventions that may improve health status may also have an impact on social support. For example, a previous qualitative study of NPMP found that by enhancing the understandings of bodily lived experiences, patients experienced that they were given the capacity to act independently and to make their own free choices regarding their own life (Sviland, Martinsen, & Råheim, 2014).

Most of the previous research related to NPMP is of qualitative design either describing the experience of treatment and examination (Dragesund & Råheim, 2008; Ekerholt, 2011; Ekerholt & Bergland, 2004, 2006, 2008; Øien et al., 2009) or discussing the epistemological conditions and conceptualization of the methodology (Bunkan, Opjordsmoen, Moen, Ljunggren, & Friis, 1999; Øien, 2010; Thornquist, 2001). In recent years, several studies on measurement properties of standardized tests have been conducted (Bunkan, Opjordsmoen, Moen, Ljunggren, & Friis, 2003; Kvåle, Skouen, & Ljunggren, 2003). However, despite the benefits of NPMP based on qualitative research, there is limited quantitative research examining the effect of NPMP, and, because of this, representatives of conventional medicine criticize psychomotor physiotherapy, stating that the treatment is considered alternative or complementary (Gundersen, 2013).

Few studies have investigated the effect of NPMP treatment. A prospective study by Aabakken, Aabakken, Øfsti, Schröder, and Wilhelmsen (1992) that included 152 patients with chronic pain receiving NPMP showed that after two and a half years, 72% of the patients had achieved significant improvement regarding pain symptoms and everyday coping (Aabakken et al., 1992). A nonrandomized trial by Breivte, Hynninen, and Kvåle (2010) included 62 patients with long-lasting musculoskeletal pain, 40 received NPMP as individual therapy and 22 were on a waiting list for such treatment. The study showed that after 1 year, the 40 patients experienced reduced depression, anxiety, insomnia, fatigue, and improved quality of life, whereas the patients on a 6-month waiting list had not changed (Breivte et al., 2010). Furthermore, one randomized controlled trial (RCT) of NPMP has been performed, although given as group therapy only examined the effect of a multimodal treatment programme for patients with long-lasting musculoskeletal pain (Anderson, Strand, & Råheim, 2007). The study indicated that the participants receiving NPMP group treatment achieved fewer tender points, reduced distribution of pain, and a higher rate of return to work after 1 year, compared with the participants in the control (CT) group. In this study, the dropout in the treatment group was large, making the results questionable (Anderson et al., 2007). Lastly, one-group prospective observational study of patients with low back pain receiving NPMP showed that nine of the 12 included patients improved significantly regarding pain, flexibility, and ability to relax (Alstad, Stiles, & Fladmark, 2011).

Summing up, few studies have investigated the effect of NPMP and no RCT of the treatment approach as an individual treatment has been performed. Thus, our primary aim was to conduct an RCT to assess if a 6-month intervention of NPMP had an effect on HRQOL. Furthermore, we examined the effect of the intervention on *pain, self-esteem, coping, and social support*.

2 | METHODS

2.1 | Study design

The study was a single-blinded pragmatic RCT comparing an intervention (IT) group with a CT group. The IT group received NPMP once weekly over 6 months, whereas the CT group received no intervention. Measurements were done at baseline and 6 months after baseline. The order of the following section follows the CONSORT statement (Schulz, Altman, & Moher, 2010).

2.2 | Study setting and patient recruitment

The participants were recruited by 36 physiotherapists working in private practice and specialized in NPMP. Persons who already waited for NPMP treatment were recruited to the study. The included persons in the study were randomized to IT or CT group. Those in the CT group remained on a waiting list for 6 months, before they were offered NPMP treatment.

The intervention and assessments were conducted at the physiotherapists' private practice clinics. Before baseline testing, the participants provided a written informed consent. A total of 105

participants were recruited, 55 to the IT group and 50 to the CT group. Figure 1 presents the flow of participants in the study. Recruitment was stopped after 2 years because of a limited time frame.

2.3 | Inclusion and exclusion criteria

Inclusion criteria were as follows: (a) referred to NPMP by a general practitioner and (b) must be at least 18 years old and able to give informed consent. Exclusion criteria were as follows: (a) does not understand Norwegian and, (b) for the CT group, had current NPMP treatment in a clinic different to the one they were on the waiting list for. No one was excluded based on these criteria.

2.4 | Randomization and blinding

The study participants were randomly allocated to two groups via concealed allocation by the researchers who designed the study. These researchers only had the participant ID number available and were not involved in the intervention or evaluation. The participants

were randomly assigned in a 1:1 ratio to the IT or CT group. Drawing lots was used to allocate the participants. Following randomization, the participants were informed by telephone which group they were allocated to. Due to the nature of the intervention, it was not possible to blind the participants or physiotherapists to group allocation. Assessment cannot be considered blinded because the outcome measures were all self-reported.

2.5 | Study intervention

The IT group received individually adapted NPMP once a week for 6 months. This duration was chosen based on previous research (Breitve et al., 2010). We have added a more thorough description of NPMP treatment in Appendix S1. In short, NPMP aims to integrate the mind-body connection with lived experience by therapeutic reflection, movement/exercises, and massage. The NPMP is based on the assumption that patients with long-lasting problems, physical and/or psychological, may react with general aberrations related to posture, respiration, and movements, as well as with muscular tension

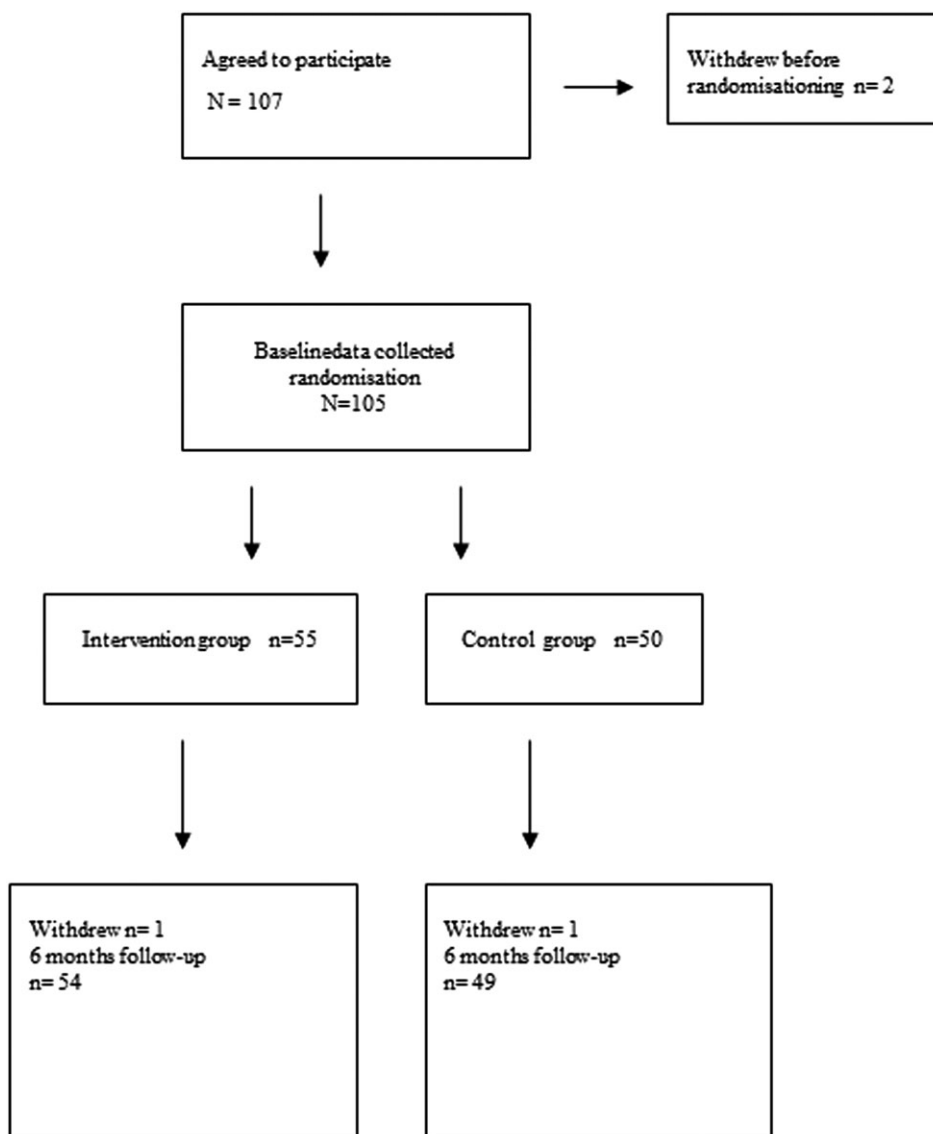


FIGURE 1 Flow of participants in the study

and skin changes (Kvåle & Ljunggren, 2007). Breathing and feelings are considered interdependent factors, and the primary difference between the NPMP examination and that of so-called traditional physiotherapy is the emphasis on respiration and body awareness (Ekerholt & Bergland, 2004). During the treatment, techniques such as relaxation, massage, and movement trainings are used for normalizing respiration and muscular control and helping the patient to become aware of how the body and mind interact (Bunkan, 2001). Thus, the intervention was individually tailored to each participant, but with the same approach of NPMP (see Appendix S1). All the physiotherapists had received a 1-year postgraduate education in NPMP, which qualifies as a specialty within the Norwegian Physiotherapy Association. This might ensure adherence to the main principles and guidelines of NPMP (Bunkan, 2001).

The CT group received no intervention as they remained on the waiting list for 6 months whereas the IT participants received NPMP. These participants were inquired to continue their daily activities as before, and not to start NPMP elsewhere while taking part in the study.

2.6 | Assessments at baseline and 6 months follow-up

Demographic data on age, gender, living arrangement, years of education, sick leave, and disability pension as well as self-reported health complaints (Eriksen, Ihlebæk, & Ursin, 1999) were collected.

2.7 | Self-reported health complaints

The Subjective Health Complaints Inventory (SHC Inventory) is a validated instrument commonly used in different populations and countries, examining self-reported health complaints during the last month (Eriksen et al., 1999; Ihlebæk et al., 2002). The instrument measures 29 subjective, somatic, and psychological complaints experienced during the last month. Severity of each complaint is rated on a 4-point Likert scale, 0 = no complaints to 3 = severe complaints (range 0–87). The questionnaire evaluates five domains: musculoskeletal pain (headache, neck pain, upper back pain, low back pain, arm pain, shoulder pain, migraine, and leg pain, range 0–24), “pseudoneurology” (tiredness, sleep problems, anxiety, sadness/depression, extra heartbeats, heat flushes, and dizziness, range 0–21), gastrointestinal problems (gas discomfort, stomach discomfort, diarrhoea, constipation, gastritis/ulcer, heartburn, and stomach pain, range 0–21), allergy (allergies, breathing difficulties, eczema, and asthma, range 0–15), and flu (cold/flu and coughing, range 0–6; Eriksen et al., 1999). In this study, we were interested in the prevalence of each complaint (no complaint [score = 0] vs. complaint [score > 1]; Ihlebæk et al., 2002).

2.8 | Primary outcome variable

All participants were asked to complete the self-report tests at baseline and 6 months after baseline.

The primary outcome of HRQOL was measured by the Short Form 36 Health Survey (SF-36; Ware & Sherbourne, 1992). This is a generic and validated questionnaire, which is translated into Norwegian (Loge & Kaasa, 1998; Loge, Kaasa, Hjermstad, & Kvien, 1998). The 36 items in SF-36 are grouped into eight dimensions:

Physical Functioning, role limitations due to physical problems (Role Physical) and emotional problems (Role Emotional), Bodily Pain, General Health perception, Vitality, Social Functioning, and Mental Health (Ware & Sherbourne, 1992). Regarding responsiveness, previous studies have calculated a minimally clinically important difference (MCID) of 5–10 points between groups for SF-36 (Wang, Beyer, Gensichen, & Gerlach, 2008). SF-36 is considered to have good validity and reliability, where the reliability coefficient is between 0.70 and 0.90 (Ware, 2000).

The Cronbach's alpha (CA) for the different domains ranged from 0.76 to 0.94 in this study.

2.9 | Secondary outcome variables

2.9.1 | Pain

Pain was measured with the Numeric Pain Rating Scale (NPRS; Downie et al., 1978). It consists of three items representing pain at three different points in time (current, best, and worst in past 24 hr) and is scored on a scale from 0 to 10 giving a minimum score of 0 and a maximum of 30, and higher scores indicate greater pain. In this study, CA for this scale was 0.93.

2.9.2 | Coping

Coping was measured using the “7-item coping scale” (Pearlin & Schooler, 1978). The “7-item coping scale” contains seven questions about the respondents' perception of coping, such as whether or not they perceive little control over what happens, whether what happens is dependent on themselves, whether some problems cannot be solved at all, and whether or not the respondents believe they can do something to change their life situations (Pearlin & Schooler, 1978). As pointed out by Pearlin and Schooler (1978), “Coping, in sum, is certainly not a unidimensional behaviour. It functions at a number of levels and is attained by a plethora of behaviours, cognitions, and perceptions” (pp. 7–8). The items in the scale are summed up to an added index ranging from 7 to 35, where higher scores indicate better coping perceptions (Pearlin & Schooler, 1978). In the present study, CA for this scale was 0.68.

2.9.3 | Self-esteem

Rosenberg Self-Esteem Scale (Rosenberg, 1965a) was used to assess self-worth and attitudes towards the self. The Rosenberg Self-Esteem Scale is a 10-item scale that requires participants to directly report feelings about the self. Examples of questions are as follows: I feel that I'm a person of worth, at least on equal with others. I feel that I have many good qualities. All in all, I am inclined to feel that I'm a failure. I can do things as well as most other people. Participants responded to these items on a 5-point Likert scale, ranging from *strongly agree* (1) to *strongly disagree* (5) giving a minimum of 10 and maximum of 50 points summary score (Rosenberg, 1965a). We calculated the CA at 0.92.

2.9.4 | Social support

Social support was measured using the Oslo-3 Social Support Scale consisting of three questions: *How easy can you get help from neighbours if you should need it? How many people are so close to you that*

you can count on them if you have serious problems? How much concern do people show in what you are doing? (Dalgard et al., 2006). Response categories were assessed independently for each of the three questions, and a sum score ranging from 3 to 14 was created based on the raw scores. The Oslo-3 scale has been used in several studies, which have confirmed its feasibility and predictive validity with respect to psychological distress. CA was 0.57 for this scale in this study.

2.10 | Ethics

The study was approved by the Regional Committee for Medical Ethics in south-east of Norway (ref. 2013/1913/REK South-East). This trial is registered in <http://clinicaltrials.gov> with ref. NCT02282007.

2.11 | Statistical analyses

Sample size was based on the primary outcome of HRQOL, SF-36. To obtain 80% statistical power ($\beta = 0.8$) at 5% significance level ($\alpha = 0.05$) with an independent samples *t* test, expecting a mean difference of 10 and standard deviation of 20, a total of 120 patients was needed (Bland & Altman, 1991). We performed an intention-to-treat analyses with the last-value-carried-forward, that is, baseline data, as imputing method for missing data during follow-up (Twisk & de Vente, 2002). We also conducted a per protocol analysis to compare results. CA was calculated for all the reported outcome measure. Guidelines for interpreting CA are as follows: unsatisfactory when <0.7 ; satisfactory at 0.7–0.79, good at 0.8–0.89, and excellent when >0.9 (Evers, Hagemester, & Hostmaelingen, 2013).

To examine the effect of the intervention, independent sample *t* tests were performed with the “difference in mean values,” delta ($=\Delta$, posttest result – baseline result). This was done to adjust for the baseline values of these measurements. To further investigate the findings and explore how other variables influenced the effect of the intervention, linear regression analyses, unadjusted and adjusted, were carried out. The statistical assumptions of linear regression models were assessed with graphical methods as, for example, residual plots. Gender was not included as a covariate in the models, owing to the low number of males within each group, and because the distribution of males and females was reasonably similar in the two groups. The variables that were found to be significantly ($p < 0.05$) associated with the dependent variable in univariate linear regression analyses were included into multivariate analyses together with the variables age and gender. In addition, we estimated effect size Cohen's *d* for all outcomes. Cohen's *d* was calculated as the difference between the means divided by the pooled standard deviation (Cohen, 1977). Guidelines for interpreting effect size is 0.2 for small, 0.5 to 0.6 for moderate, and 0.8 to 1.0 for large changes (Cohen, 1977). A two-sided *p* value less than or equal to 0.05 was considered statistically significant, but due to repeated testing, we used Bonferroni correction, resulting in a significance level of $p = 0.004$. All statistical analyses were performed with the IBM SPSS Statistics version 22.

2.12 | Missing data

The data file was screened for missing items and few missing items ($<2\%$) appeared.

3 | RESULTS

Regarding the flow of participants through the study, we did not collect information on how many that declined to participate in the study after being assessed for eligibility. Of the 105 referred to intervention, two participants did not complete the last assessment at 6 months (see Figure 1). Seven people withdrew before intervention, three in the IT group and four in the CT group. The latter four stated that they withdrew due to disappointment for not being allocated to the IT group. Two people withdrew during treatment for unknown reasons, one from the IT group and one from the CT group.

Demographics of the 105 participants are presented in Table 1. Of the total sample, 95 (90.5%) were women. Mean age was 41.9 years, the youngest participant was 19 years old, and the oldest was 76. A total of 51.9% of the participants reported that they were on sick leave from work at the time of assessment. In addition, 10.6% of the participants were on disability pension and 13.9% were unemployed.

With regard to the health complaints of the participants, Table 2 presents the sample's prevalence of subjective health complaints measured by the SHC Inventory along with reference values for a normal

TABLE 1 Demographics of participants $N = 105$.

Age, year				
\bar{x}		41.9		
SD		12.0		
Range				
		19-76		
	Number	Percentage	Lower 95% CI	Upper 95% CI
Age groups, year				
18-29	16	15.2	8.2	22.2
30-39	30	28.6	19.8	37.4
40-49	34	32.4	23.3	41.5
50-59	16	15.2	8.2	22.2
60-69	7	6.7	1.8	11.5
70+	2	1.9	0.0	4.6
Gender				
Women	95	90.5	84.8	96.2
Men	10	9.5	3.8	15.2
Education				
Primary ed.		17.7	10.1	25.2
High School	24	23.5	15.2	31.9
Higher ed.	60	58.9	49.1	68.5
Unanswered	3			
Status				
Single	28	26.7	18.1	35.3
Married or cohabitant	71	67.6	58.5	76.7
Divorced or widow(er)	6	5.7	1.2	10.2
On sick leave	54	51.9	42.2	61.7
On disability pension	11	10.6	4.6	16.6
Unemployed	14	13.9	7.0	20.7

CI: confidence interval for the percentage; ed: education; SD: standard deviation; \bar{x} : mean

TABLE 2 Percentage of persons reporting subjective complaints experiences in the last 30 days before baseline (score over 0) in the study sample ($n = 105$, age 18–76) compared with a Norwegian population ($n = 1,240$, age 15–84)

Subjective complaints	Our sample	Normal population Norwegian (Ihlebaek et al., 2002)
Musculoskeletal pain		
Headache	79.8	50.6
Neck pain	61.5	37.8
Upper back pain	68.9	18.8
Low back pain	73.1	39.7
Arm pain	44.9	23.4
Shoulder pain	78.4	42.4
Migraine	24.3	7.6
Leg pain	40.4	28.4
Pseudoneurology		
Extra heat beats/palpitations	39.0	19.5
Heat flusher/hot flushes	37.5	13.0
Sleep problems	70.5	30.3
Tiredness	90.5	52.8
Dizziness	61.0	20.5
Anxiety	49.5	14.2
Sadness/depression	59.0	26.8
Gastrointestinal problems		
Heartburn	31.4	30.5
Stomach discomfort	30.1	23.3
Ulcer/nonulcer	20.0	10.3
Dyspepsia gas discomfort	22.9	38.9
Diarrhoea	36.5	23.7
Obstipation	36.7	12.6
Stomach pain	26.2	23.3
Allergy		
Asthma	9.6	11.0
Chest pain	25.7	20.0
Breathing difficulties	25.0	15.5
Eczema	21.0	17.6
Allergies	24.8	14.8
Flu		
Cold/flu	34.3	53.1
Coughing	25.0	33.1

Norwegian population. The participants in this study had higher prevalence of each complaint than the normal population on all, but four health complaints (flu, dyspepsia, and asthma). The differences were particularly evident in the musculoskeletal pain and pseudoneurology areas (Table 2).

Further assessments of the study participants showed that those with years of education of 12 years or more were significantly older ($p = 0.02$) and reported more bodily pain on the SF-36 domain ($p = 0.04$) as well as more pain recorded with the NPRS ($p = 0.009$) compared with those with less than 12 years education. Those with higher level of education had a mean age 39.6 and a mean score on SF-36: Level of Bodily Pain was 39.6, and the mean score of pain reported by NPRS was 14.6 compared with those with level of education less than 12 years who had a mean age of 45, mean SF-36 body

TABLE 3 Baseline scores on primary and secondary outcomes for all participants ($N = 105$)

The dimensions of health-related quality of life ^a	Score in point (%)
Physical Functioning: mean (SD)	77.3 (17.9)
Role Physical: mean (SD)	53.3 (30.8)
Bodily Pain: mean (SD)	38.4 (21.2)
General Health: mean (SD)	49.0 (23.0)
Mental Health: mean (SD)	62.3 (17.7)
Role Emotional: mean (SD)	66.8 (27.1)
Social Functioning: mean (SD)	57.7 (25.8)
Vitality: mean (SD)	29.0 (18.2)
Pain, coping, self-esteem, and social support	
NPRS (pain): mean (SD)	16.1 (6.7)
Coping: mean (SD)	24.4 (4.7)
Self-esteem: mean (SD)	35.0 (6.9)
Social support: mean (SD)	10.4 (2.1)

Note. NPRS: Numeric Pain Rating Scale and higher scores indicate greater pain; SD: standard deviation.

^aHigher scores indicate better health-related quality of life.

pain score of 20.4, and mean NPRS score of 18.1, respectively. We found no major difference in gender and the other baseline characteristics between the randomized groups (Tables 1, 2, and 3).

Table 4 presents the results of the study. After 6 months of NPMP, participants in the IT group significantly improved their scores on the SF-36 dimensions of Physical Functioning, Role Physical, Bodily Pain, General Health, Mental Health, Role Emotional, Social Functioning, and Vitality (Table 4). A significant difference between the two groups was observed in six of the eight SF-36 domains: Physical Functioning, Bodily Pain, General Health, Mental Health, Social Functioning, and Vitality (Table 4). The Cohen's d effect sizes on SF-36 dimensions ranged from 0.9 for Vitality to 0.3 for Role Physical and Role Emotional with a median of 0.6. At 6 months, there was a significant improvement in coping in both groups, but no significant difference between the groups was found (Table 4).

The participants in the IT group reported better results regarding self-esteem and less pain reported by NPRS. Furthermore, there was a significant difference between groups regarding self-esteem and pain, in favour of the IT group (Table 4). Effect size for pain was 0.9 and for self-esteem 0.6. No significant differences between groups were observed regarding the two SF-36 domains of Role Emotional and Role Physical, nor was there a difference regarding the measure of social support (Table 4). The per protocol analysis produced equivalent results as the Intention-to-treat analysis (ITT) analysis (results not shown).

3.1 | Adverse events

No adverse events were recorded during the intervention period.

4 | DISCUSSIONS

The results of this first RCT of NPMP demonstrate a pronounced effect of a 6-month intervention of NPMP upon the primary outcome

TABLE 4 Effect of the intervention on health-related quality of life (SF-36), pain, coping, self-esteem, and social support

Variables	Intervention group (n = 55)				Control group (n = 50)				Mean change between groups			
	Baseline mean (SD)	6 months mean change	6 months mean change [95% CI]	p**	Baseline mean (SD)	6 months mean change	6 months mean change [95% CI]	p**	Change mean	[95% CI]	p*	Effect size Cohen's d
Physical Functioning	75.7 (20.0)	9.85	[6.34, 13.37]	<0.001	79.2 (15.2)	0.11	[-4.36, 4.57]	0.80	8.79	[3.55, 14.01]	0.001	0.5
Role Physical	56.0 (29.9)	10.96	[3.36, 18.56]	0.004	50.3 (30.3)	2.08	[-8.45, 12.61]	0.58	9.18	[-2.07, 20.44]	0.11	0.3
Bodily Pain	38.2 (19.5)	23.48	[16.14, 30.81]	<0.001	38.7 (23.2)	6.50	[-1.34, 14.34]	0.09	16.77	[7.60, 25.95]	<0.001	0.8
General health	48.1 (23.3)	15.98	[11.15, 20.80]	<0.001	49.9 (22.8)	4.81	[-2.99, 12.61]	0.32	12.32	[4.11, 20.53]	0.003	0.5
Mental health	55.6 (13.3)	12.31	[8.27, 16.35]	<0.001	60.4 (14.8)	1.22	[-4.26, 6.7]	0.73	10.62	[4.75, 16.49]	0.001	0.8
Role emotion	53.0 (21.3)	13.97	[8.84, 19.09]	<0.001	54.3 (22.4)	7.59	[-2.07, 17.26]	0.12	7.12	[-2.01, 16.25]	0.12	0.3
Social functioning	53.4 (27.2)	20.54	[11.77, 29.30]	<0.001	62.0 (23.7)	6.25	[-1.28, 13.78]	0.29	16.41	[5.25, 27.57]	0.004	0.6
Vitality	32.4 (13.8)	16.96	[12.82, 21.09]	<0.001	34.0 (15.7)	4.40	[-0.47, 9.26]	0.06	13.13	[7.41, 18.85]	<0.001	0.9
NPRS (pain)	15.9 (6.6)	-6.6	[-8.7, -4.63]	<0.001	16.4 (6.9)	-0.67	[-2.43, 1.10]	0.39	-5.35	[-7.80, -2.90]	<0.001	0.9
Coping ^a	23.9 (4.6)	2.40	[1.20, 3.61]	<0.001	24.9 (4.7)	1.33	[-0.02, 2.68]	0.01	0.91	[-0.68, 2.50]	0.26	0.2
Self-esteem ^a	33.9 (6.4)	4.95	[3.24, 6.66]	<0.001	36.3 (7.2)	0.67	[-1.15, 2.48]	0.66	4.39	[2.10, 6.68]	<0.001	0.6
Social support ^a	10.4 (2.1)	0.19	[-0.37, 0.75]	0.37	10.4 (2.1)	-0.44	[-1.25, 0.36]	0.19	0.69	[-0.14, 1.53]	0.10	0.3

Note. CI: confidence interval; NPRS: Numeric Pain Rating Scale and higher scores indicate greater pain; SD: standard deviation.

^aHigher scores indicate better results.

*p significant difference between the IT group and the CT group based on independent t test. **p significant difference between baseline and 6 months based on paired t test.

of HRQOL measured by the SF-36. Furthermore, the IT group reported significantly less pain and improved self-esteem compared with the CT group.

We reached a sample that corresponds to previous research describing patients referred to NPMP (Aabakken et al., 1991; Breivte et al., 2008; Kamps & Arnesen, 2004; Kvåle et al., 2001; Malmgren-Olsson & Armelius, 2003; Thornquist & Bunkan, 1991). The majority of the sample was women, and mean age was 42 years. With regard to subjective health complaints as described by the SHC Inventory, the participants scored higher than the normal population in all but four domains (Ihlebak et al., 2002); higher scores were particularly evident in symptoms of musculoskeletal pain and pseudoneurology. Of the sample, 13.9% reported that they were unemployed, which is more than the normal population in Norway, which has an unemployment rate of 4.9% (Statistics Norway, 2016). Furthermore, the average score for coping in the sample was 24.2, which is 3.1 lower than the population's average score of 27.3 (Clench-Aas, Nes, & Aarø, 2017). The patients thus reported significantly lower coping than the Norwegian population (Clench-Aas et al., 2017). When it comes to pain, the sample had pain over the medium when compared with previous research on classification of pain (Boonstra et al., 2016; McCaffery & Beebe, 1989). Furthermore, the baseline registration of HRQOL in our sample was significantly poorer compared with the general population (Dagfinrud, Mengshoel, Hagen, Loge, & Kvien, 2004); considering that quality of life is increasingly emphasized in health policy guidelines for health services, this makes them a priority group among health-service users (Ringard, Sagan, Sperre Saunes, & Lindahl, 2013). Good HRQOL is seen as an overall good and as a prerequisite that affects the individual's welfare and health (Bergland & Narum, 2007a, b). Råheim and Håland's (2006) study indicates that HRQOL is reduced in patients with fibromyalgia and long-standing pain.

Our results are in line with the nonrandomized, nonblinded study of Breivte et al. (2010). In their study, the participants reported improved HRQOL measured by "Quality of life inventory" (Frisch, 1994) after a 6-month intervention of NPMP. Eighty-two per cent of the total sample of 62 participants were women, and the mean age was 44.3 years; 40% in the treatment group had higher education (>12 years); and half of them (50%) were on sickness leave or on disability pension all of which corresponds quite well with our results (Breivte et al., 2010). The positive effect of NPMP on pain in our study is also in line with the findings of the RCT by Anderson et al. (2007) where the group receiving NPMP as group treatment achieved fewer tender points and a reduced distribution of pain. Two other prospective studies, although with a weaker design, also indicate that NPMP can reduce long-standing pain (Aabakken et al., 1991; Alstad et al., 2011).

In addition, we found our results to be in line with two previous qualitative studies by Ekerholt and Bergland (2006, 2008), which concluded that during NPMP, patients became more able to recognize and verbalize, body sensations, gradually growing more familiar with their own emotions and feelings that they found useful in their daily life. A parallel can be drawn between these qualitative findings and the improvements we found in HRQOL, self-esteem, pain, and coping in the IT group of this study.

This study has some limitations. First, by ethical necessity, this was a convenience sample meaning that only the ones interested in and motivated by the study participated. Intervention studies involving

physiotherapy tend to appeal to healthier and better motivated individuals (Pacala, Judge, & Boulton, 1996). Also, the number of people who declined to participate was, unfortunately, not registered. The number of included participants was somewhat lower than the planned sample sized to obtain 80% statistical power. However, the study found statistically and clinically significant changes in most of the outcome measures.

This study has a pragmatic design with 36 physiotherapists working in private practice and specialized in NPMP conducting an NPMP intervention in private practice. Such an approach has both strength and limitations. Generalizability to a clinical setting improves. This could have limited self-selection bias and increased the representativeness by providing a clinically relevant sample. On the other hand, this pragmatic design makes it difficult to ensure homogeneity of the intervention. Furthermore, one can question whether intervention once a week for 6 months was sufficient. It is unclear whether participants improved as much as possible over this period or whether the intervention ended before they had reached their full potential. Furthermore, we did not collect information about level of habitual physical activity in our sample. Thus, we cannot control for additional physical activities and how that may have contributed to the results. The Hawthorne effect should also be considered (Merrett, 2006). Finally, the outcome measures are subjective and potentially affected by the amount of motivation or participants' satisfaction or dissatisfaction with group allocation. Because the controls only received usual care, some participants might have initiated treatment themselves such as joining an exercise group.

Regarding study strengths, being the first RCT of NPMP as individual treatment, this study is highly relevant. A strength of the study is the design, as RCTs are the most robust evaluative method (Puffer, Torgerson, & Watson, 2005). The primary outcome measure of HRQOL reinforces this relevance.

Of importance to the interpretation of the results is the responsiveness of the SF-36, which refers to the detection of a change that is clinically relevant or meaningful from the patient's perspective, also called MCID (Haywood, Garratt, & Fitzpatrick, 2005; Perera, Mody, Woodman, & Studenski, 2006). Previous studies have calculated an MCID of 5–10 points between groups for SF-36 (Wang et al., 2008). In this current study, the mean SF-36 score changes in the IT group ranged between 9.85 and 23.48, indicating that the results for HRQOL were not only statistically significant but also represented a meaningful improvement to the patients. Further proofs of clinical significance are the effect sizes, which were moderate to large on six of the domains of the HRQOL measure and moderate to large for pain. Moreover, the low dropout rate and the lack of adverse events might also be an indication that the intervention was not only effective but also feasible. The present results contribute to a better understanding of the feasibility and effect of NPMP intervention. The fact that the statistical difference in HRQOL also showed clinical significance makes the results valuable for clinical practice.

4.1 | Clinical implications

The results of this study indicate that NPMP, which is a safe, relatively low-cost, and nonpharmacologic intervention, may enhance HRQOL

and self-esteem and decrease self-reported pain among community-dwelling adult people who are referred to NPMP.

5 | CONCLUSION

In this study, we have demonstrated that NPMP is an effective and safe intervention for adults living in the community. NPMP led to significantly greater improvement in HRQOL measured by SF-36, as well as increased coping and self-esteem and reduction in pain for those in the IT group compared with those in the CT group. To strengthen the level of evidence, future studies are needed. Future research should focus on exploring the long-term effect of NPMP on quality of life in this population as well as to assess the replicability of our results.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

ETHICAL APPROVAL

The study was approved by the Regional Committee for Medical Ethics in south east of Norway (ref. 2013/1913/REK South-East).

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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