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Chapter 4

A randomized controlled trial targeting motivation and self-regulation to increase physical activity among patients with rheumatoid arthritis

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Submitted
A Self-regulation Intervention to Increase Physical Activity

Abstract

Objective: To evaluate whether a 5-week intervention that targets both the motivation and action phases of behavior change leads to increased physical activity (PA) among insufficiently active patients with rheumatoid arthritis (RA).

Methods: Seventy-eight patients with RA who did not meet the 5x30 minutes recommendations for healthy PA were randomly allocated to receive a group-based patient education session led by a physical therapist (control), or the education session plus a motivational interview and 2 self-regulation coaching sessions led by a physical therapist and a rheumatology nurse respectively (treatment). At baseline, 6-weeks and 32-weeks patients in both groups filled-in questionnaires assessing self-efficacy and autonomous motivation for PA, leisure-time PA, and days per week with at least 30 minutes of moderate-intensity PA; and the secondary outcomes disease activity, functional status, depressive symptoms and fatigue.

Results: The intervention had significant effects over time on self-efficacy, autonomous motivation, leisure-time PA and active days/week compared to the control group. At 6-weeks, 67% and 23% of the treatment and control groups met the 5x30 recommendation for healthy PA. At 32 weeks, these percentages were 48% and 25%, respectively. Furthermore, the treatment group reported significant reductions in depressive symptoms and fatigue at 6-weeks.

Conclusion: This minimally resource-intensive intervention combined motivational interviewing and self-regulation coaching, and led to sustained increases in PA which may be attributable to changes in self-efficacy and autonomous motivation for PA. Programs emphasizing patients’ personal goals and motivations when promoting PA among patients with RA may help maintain changes in behavior.
Significance and Innovations

- This pilot intervention was the first to combine motivational interviewing and self-regulation coaching to promote physical activity (PA) among insufficiently active patients with RA.
- The intervention, which targeted both the motivation and action phases of behavior change, had significant effects on autonomous motivation and self-efficacy for PA, as well as on leisure-time PA.
- Despite only 5 hours of contact time per patient, rates of PA initiation and maintenance were higher than those achieved by more resource-intensive interventions which only targeted the action phase of behavior change.
The importance of physical activity (PA) for patients with rheumatoid arthritis (RA) is well documented [1], and PA promotion forms part of recommended care for these individuals [2]. Despite this, many RA patients do not undertake regular PA, and most do not meet the recommended norm of 30 minutes of moderate-intensity PA on 5 days of the week (5x30 recommendation)[3, 4]. These facts, coupled with the elevated risk of cardiac events and cardiac-related mortality within this patient group [5], have led to the development and implementation of several interventions to increase PA among patients with RA. A recent review indicates that such interventions lead to large increases in PA behavior, and to small improvements in pain and both subjectively and objectively measured functional ability [6].

Among patients with arthritis, interventions to increase PA often employ strategies derived from self-regulation theory [7], including behavioral goal setting, action planning, self-monitoring of behavior, feedback about progress toward goals, and problem solving strategies [8, 9]. Such interventions may alternatively (or in addition) include supervised exercise sessions, PA prescription and/or contracting about PA behavior [6]. Although most of these interventions have led to short-term increases in PA, they focus solely on the action phase of behavior change, paying little attention to the motivational aspects of behavior change: a deficit that may explain decreases in the effects of these interventions over time [10, 11].

According to several prominent behavior change theories, the action phase of behavior change is preceded by a motivational stage, in which changes in cognitions lead to the formulation of outcome goals or intentions [12]. As strong intentions are more readily and consistently translated into behavior [13], interventions targeting cognitions which strengthen intentions might lead to better uptake and maintenance of behavioral changes, particularly when coupled with the self-regulation strategies described above [14, 15]. Two cognitions of particular importance in the motivational phase of physical activity behavior change are self-efficacy and autonomous motivation for physical activity.

Self-efficacy for PA is the extent to which an individual believes he or she could be physically active across a variety of situations, including when faced with barriers to PA such as pain, bad weather or a busy schedule [16]. Higher levels of self-efficacy for PA predict higher levels of PA, both among patients with RA [17] and in the general population [18], so increasing self-efficacy is important when promoting PA, particularly among individuals who are not already physically active [19]. As self-efficacy for PA is greatly affected by successful, positive experiences with PA [20], interventions targeting it try to
increase the likelihood of such experiences occurring. This is best done utilizing the same set of self-regulation techniques described earlier, but tailored toward small, measurable achievements and limiting failures when pursuing PA goals [21].

Another variable underlying PA behavior is autonomous motivation for PA, or the extent to which one participates (or would participate) in PA because it is personally important, as opposed to doing so because it is valued or chosen by someone else (e.g. spouse, doctor) [22]. As autonomous motivation predicts sustained PA among patients with RA [23], PA interventions that target this variable may yield better long term maintenance of behavioral changes. In terms of methods to increase autonomous motivation for PA, motivational interviewing (MI) is one therapeutic technique believed to do so [24], but to date, its efficacy at increasing autonomous motivation has scarcely been investigated [25].

The present study aimed to examine the effects of an intervention to promote PA, which included both motivational and action phase-related components. This pilot randomized controlled trial, among individuals with RA not meeting the 5x30 recommendation, compares the effects of an intervention which combines patient education, motivational interviewing (MI) and self-regulation coaching to specifically target the psychological variables autonomous motivation and self-efficacy for PA, to patient education alone. Aside from testing the effects of the intervention upon these psychological variables and physical activity, the effects of the intervention upon disease activity, functional status, depressive symptoms and fatigue will also be examined.

**Participants and Methods**

**Study Design**

This randomized controlled pilot study was approved by the Leiden University Medical Center Ethics Review Board and was conducted between August 2010 and November 2011. A detailed protocol is registered with the Netherlands Trial Register (http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=2240). All patients provided informed consent after being informed that they would at least be provided with advice on PA and information about PA opportunities in the area.

**Participants and Procedures**

Potential participants were identified through registers of patients who had attended the outpatient rheumatology department of either Leiden
University Medical Center, HAGA Hospital in The Hague, or Reinier De Graaf Gasthuis in Delft. To be eligible for inclusion, patients must have been at least 18 years of age and diagnosed with RA according to the American College of Rheumatology criteria [26].

Those identified as eligible for participation were randomly selected in groups of 250 and were mailed leaflets describing the physical activity program tested in this study. Participants who responded with interest in participating were screened via telephone, and were excluded if they reported 30 minutes of moderate-intensity physical activity on 5 or more days each week, had received physical therapy for their RA within the last six months, had difficulty ambulating, or could not attend the treatment sessions due to scheduling or transportation issues. Remaining patients who provided informed consent were randomly assigned and allocated to either the control or intervention group using a random number generator. After randomization, patients were mailed a baseline questionnaire that was to be returned 1-2 weeks later, when they attended a group patient-education meeting.

Power calculations using a power level of 0.8 and alpha of 0.05, and based on the findings of a meta-analysis of PA interventions among individuals with arthritis ($d = 0.69$) [6] and an intervention which targeted PA increases among sedentary individuals with RA (a 24% between-groups difference of people meeting the 5x30 recommendation at post-treatment) [27], indicated required sample sizes of 35 and 38 per group, respectively. Groups of eligible patients were mailed leaflets until at least 38 participants had been allocated to each condition.

The researcher who conducted randomization and allocation (EH) was not involved in data analysis, and the allocation code was concealed from other researchers until after all data had been prepared for analysis.

**Demographic characteristics.** Data on age, sex, body mass index, employment, education levels obtained and use of non-steroidal anti-inflammatory medications were collected from questionnaires filled-in at baseline.

**Primary outcome measures.** Physical activity (PA) was assessed by means of two self-report measures. The Short Questionnaire to Assess Health-Enhancing Physical Activity [28] assessed leisure-time PA. In this questionnaire, participants were asked how many days per week and minutes per day they engaged in walking, cycling and sporting activities in spare time. For each activity, days per week were multiplied by minutes per day, and these products were summed to calculate minutes per week of leisure-time PA.
Additionally, participants answered one question to determine whether they met the Dutch PA recommendation of 5 days per week with at least 30 minutes of moderate intensity PA (5x30 recommendation) [29]. This single item has been used in previous interventions to promote PA among sedentary individuals with RA [27], and asks individuals on how many days per week they engaged in at least 30 minutes of moderate intensity PA over the last month. The question is preceded by a description of the effects of moderate-intensity PA (e.g. increased heart-rate) and forms of moderate-intensity PA (e.g. brisk walking, cycling).

Self-efficacy for PA was assessed using the 18-item self-efficacy scale created by Bandura [30]. Each item presents a situation in which it may be difficult to engage in PA (e.g. when busy, during bad weather), and allows participants to rate the likelihood that he/she would be physically active in the given situation. Participants could respond with a number from 0 (not at all likely) to 10 (certainly), and the 18 item scores were summed to create the total self-efficacy score.

Autonomous motivation for PA was measured with 3-items from the Treatment Self-Regulation Questionnaire [31]. Each item is scored using a 7-point Likert scale with anchors of 1 (totally disagree) and 7 (totally agree), and measures the extent to which participants engaged in PA for personal reasons (e.g. enjoyment, fun), as opposed to reasons important to others. The autonomous motivation score was calculated by taking the mean of the 3 items.

Secondary outcome measures. Disease activity was measured with the Rheumatoid Arthritis Disease Activity Index (RADAI) [32]. The RADAI assesses disease activity across five domains: joint inflammation over the last 6 months, present joint tenderness/swelling, present arthritis pain, duration of morning stiffness, and present level of pain in 16 individual joints (both left and right shoulders, elbows, wrists, fingers, hips, knees, ankles and toes). Each of these domains is scored from 0-10, with higher scores indicating more disease activity. Total disease activity is calculated by taking the mean of these five domains.

Functional status was assessed with the 20-item disability scale of the Health Assessment Questionnaire (HAQ)[33]. Each item is scored on a 0-3 scale, where zero indicates no functional limitations and three indicates severe functional limitations. The mean of the 20 item scores was used as a total functional status score.

Depressive symptoms were assessed using the 6-item scale of the Brief Symptom Inventory (BSI) [34]. Participants rated each distress item from 0-4, with higher scores representing more distress. The mean of the scored items was taken as the total depressive symptoms score.
Fatigue was assessed with the 20-item Checklist of Individual Strengths (CIS-20)\cite{35}. The CIS-20 presents statements such as “I feel well rested” and “I feel physically exhausted,” to which participants respond with the extent to which the statement describes them on a 7-point scale. After reversing the appropriate items, the sum of all items produces a total fatigue score, with higher scores indicating more fatigue.

**Interventions.** All interventions took place in the Leiden University Medical Center, irrespective of recruitment site. In week one of the intervention, all patients attended a group educational session which included exclusively intervention or control participants, and provided information about the importance of physical activity for people with RA and about pacing when beginning a new activity. The session also focused on dispelling myths surrounding PA and RA, and provided patients with a list of arthritis patient organizations and exercise classes in the area. The educational session was delivered in a small group format (3-7 people) by a physical therapist who had provided similar educational talks to arthritis patients for 5 years, and who was unaware of participants’ group allocations.

In the four weeks following the education session, patients allocated to the intervention group received a one-on-one motivational interview (MI) and two one-on-one self-regulation (SR) coaching sessions. The MIs took place in week 2 or 3 of the intervention, lasted between 15 and 45 minutes, and were conducted by one of three physical therapists who had previously received four, four-hour training sessions on the delivery of MI. During the MI, patients weighed the pros and cons of (re-)engaging in regular PA, and attempts were made to link a more physically active lifestyle with long-term goals that were important to the patient (e.g. maintaining independence, being able to spend time with grandchildren). At the end of the MI, patients set a long-term (outcome) goal that could be achieved through PA, and received a folder containing an exercise diary. Patients completed the exercise diary on seven consecutive days by noting down periods of physical activity lasting at least 10 minutes, and were instructed to bring the diary along to the first self-regulation coaching session.

A rheumatology nurse delivered the two SR coaching sessions two and three weeks after the MI, in weeks 4 and 5 of the intervention, respectively. These 40-60 minute sessions followed the structure of a workbook which was developed for this study and emphasized the tenets of self-regulation theory \cite{7}. Both SR sessions began with a review of the exercise diary patients had completed in the previous week. Patients received feedback on their progress,
and worked together with the rheumatology nurse to set a short-term, realistic PA goal and create a corresponding action plan for the coming week (i.e. what physical activities would take place, as well as when, where, and for how long each would take place). At the end of each session, patients were again prompted to complete the exercise diary for the following week. Additional workbook components covered in the sessions included barrier identification and problem solving (coping planning), breaking large goals down into smaller ones, activating social support, self-reward, and the use of prompts/cues as reminders to be physically active. The behavior change techniques used in each session of the intervention are presented in Table 1.

In weeks 6, 12 and 18 of the intervention, patients in the intervention group received a follow-up phone call from the rheumatology nurse to further discuss the patient’s efforts in self-regulating his or her physical activity. These follow-up phone calls utilized the same techniques as the face-to-face sessions, and lasted between 10 and 20 minutes.

**Statistical procedures.** Between-groups differences at baseline were assessed by means of t-tests for continuous variables, and chi-square tests for categorical variables. The effects of the intervention were investigated in two separate datasets: an as-treated dataset which included individuals who had received the intervention according to the protocol and who had provided data at the given time point, and an intention-to-treat (ITT) dataset which included all participants as they were randomized, with missing values imputed using the last observation carried forward method (LOCF).

As a primary test of intervention effects, a mixed (split-plot) repeated measures ANOVA with group assignment as a between-subjects factor and time point as a within-subjects factor was run for each outcome variable within the intention-to-treat dataset. A significant interaction (P < 0.05) of the within- and between-subjects factors (Group x Time) signifies that the respective changes in outcomes of the intervention and control groups differed over time. These repeated measures analyses were controlled for age, sex, and baseline levels of disease activity.

To examine the within-group effects of the intervention, paired t-tests compared values of outcome variables at post-treatment and follow-up with their corresponding values at baseline in both datasets. Finally, chi-squared analyses examined between-groups differences in the proportion of individuals meeting the 5x30 recommendation at post-treatment and follow-up.
Results

In total, 1251 patients were mailed information about the study, 701 responded with interest in participating and were screened for eligibility, and 78 were randomized to either the MI+SR intervention group (n = 38) or the education control group (n = 40). The flow of patients through the trial and reasons for exclusions are shown in Figure 1. At baseline, the intervention group reported significantly less disease activity and included significantly more females than the control group. The groups did not significantly differ on any other demographic or disease-related variables (Table 2).

Within the intention to treat dataset, there were significant Group x Time interactions for the primary outcomes total self-efficacy, autonomous motivation, leisure time PA, and days per week with 30 minutes of PA; but not for the secondary outcomes disease activity, functional status, depressive symptoms and total fatigue (Table 3).

At post-treatment (6 weeks), the intervention group reported significant improvements in total self-efficacy, leisure time PA, days per week with 30 minutes of PA, depressive symptoms and total fatigue compared to baseline. No significant within-group changes were reported for autonomous motivation, disease activity or functional status. In the control group, only days per week with 30 minutes of PA had significantly increased from baseline.

At follow-up (32 weeks), the intervention group had maintained significant improvements from baseline in total self-efficacy, leisure time PA, and days per week with 30 minutes of PA. The control group reported significantly less autonomous motivation than at baseline, while the intervention group reported significantly more (although the latter was not found in the as-treated dataset). Depressive symptoms in the intervention group were significantly lower than baseline values (although this was not found in the as-treated dataset). Follow-up levels of total fatigue did not significantly differ from baseline levels.

At 6 weeks, a significantly higher percentage of participants in the intervention group (67%) met the 5x30 recommendation for PA than in the control group (23%). This difference decreased, but remained significant, at 32 weeks with 48% and 25% of intervention and control participants meeting the 5x30 recommendation, respectively (Table 4).

Discussion

This randomized controlled pilot study, among individuals with RA not meeting the 5x30 minutes recommendation for PA, tested an intervention that combined physical therapist-led motivational interviewing and nurse-led self-
regulation coaching to address both the motivation and action stages of behavior change. After receiving this five-week intervention, patients had significantly increased their leisure time PA by roughly 65 minutes more per week than the control group, and had also increased their number of active days per week by 1.5 over the control group.

There was also a significant increase in the percentage of individuals meeting the 5 x 30 minutes PA recommendation. Two-thirds of the participants in the treatment group met this recommendation at post-treatment, and although that percentage fell to 48% six months after the intervention, this rate was still significantly higher than the 25% of individuals meeting it in the control group and somewhat higher than the 38% who reported meeting it six months into an internet-based intervention among a similar RA population [27].

The effects of this relatively low resource-intensive intervention (less than 5 hours of total contact time including follow-up phone calls), which combined motivational interviewing and self-regulation coaching, are in contrast to those from several more resource-intensive PA interventions tested among patients with RA, which targeted only the action phase of behavior change. In recent studies, neither the 8-week People with Arthritis Can Exercise program [36], nor the 1-year PA coaching program of Brodin and colleagues (which also included patients who were physically active) [37] led to significant increases in PA behavior. This difference in outcomes lends support to the importance of addressing the motivational phase in PA interventions for individuals not meeting recommended levels of PA.

Further support is lent to this hypothesis by the significant effects of the intervention upon both self-efficacy and autonomous motivation for PA; both of which were specifically targeted by the combination of techniques included in the intervention. Although several other interventions to increase PA have increased self-efficacy for PA [36, 38], this is the first study to demonstrate an effect upon autonomous regulation among individuals with RA. Interestingly, although there was a significant group x time effect upon autonomous motivation over the course of the study, significant within-group changes in autonomous motivation did not occur until the 32-week follow-up. This may imply that the effects of motivational interviewing upon autonomous motivation take time to appear, as patients begin to internalize their once extrinsic PA goals and build repertoires of enjoyable experiences with PA [39]. Furthermore, in the control group, inactivity coupled with confronting information about PA (i.e. filling in the questionnaires) might explain how autonomous motivation decreased over time.
Although there was no significant overall effect of the intervention on depressive symptoms, the intervention group reported significant decreases in depressive symptoms at post-treatment (and at the 6-month follow-up in the intention to treat analysis). These changes may be attributable to a number of factors including dopaminergic response from PA [40], social contact received during the intervention [41] or goal achievement [42]. It should be noted that the sample had very low reports of depressive symptoms overall, so the clinical relevance of this finding might be further explored among individuals reporting higher levels of depressive symptoms.

At post-treatment, the treatment group reported a significant decrease in levels of fatigue from baseline. This is a common finding for PA interventions, and is likely attributable to improvements in muscle strength and aerobic capacity accrued through increases in PA [43, 44]. This finding should be interpreted with caution however, as the Group x Time effect on fatigue was minimal, and the change did not remain significant at follow-up.

Although this intervention led to increases in PA that were maintained at the 32-week follow-up, no such improvements occurred in disease activity, or functional status. This finding may have arisen from an incongruity between the types of PA participants undertook in this study (self-chosen, enjoyable, fun, and which they were autonomously motivated to do), and the types of PA that participants have undertaken during more structured PA interventions (suggested by others, possibly difficult or strenuous, and perhaps more likely to improve disease activity and functional ability) [45, 46]. As autonomously motivated forms of PA are more likely to be maintained in the long-term, clinicians and researchers in this area are therefore tasked with making dynamic forms of exercise more appealing to individuals with RA, and presenting targeted physical activity advice in an autonomous supportive way [47].

Despite the novelty of this study, several limitations should be discussed. First, although the study led to increases in both leisure time PA and days per week with at least 30 minutes of PA, these are both self-report measures and may be subject to response bias [48, 49]. More objective measures of PA (e.g. accelerometers) should be used in any replication of this study. Second, the design of this study makes it difficult to determine which components of the intervention led to changes in cognitions and behavior. Future investigations could test motivational interviewing and self-regulation coaching in a full-factorial design to determine whether each has individual effects on cognitions and behavior, or whether this particular combination of components is necessary to increase PA behavior. Finally, although this pilot study provides some evidence that changes in PA-related cognitions are related
to increased PA behavior, it was only powered to detect changes in PA, and the power calculations did not take potential dropouts from the study into account. Future studies should be powerful enough to specifically test whether changes in cognitions predict changes in behavior, and should consider potential dropouts when conducting power calculations.

In conclusion, this novel, theory-based intervention that targeted both the motivation and action phases of behavior change led to increases in the PA-related cognitions self-efficacy and autonomous motivation, as well as to increases in physical activity that were maintained at 32-weeks follow-up. Although no changes were reported in disease activity or functional status as a result of the intervention, the fact that it was delivered by physical therapists and nurses typically involved in the treatment of patients with RA, and led to increased PA with a minimal amount of contact time, makes it a good starting point for promoting PA among insufficiently active individuals in clinical practice.

**Acknowledgments**

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Figure 1. Flow of participants through the intervention

Mailed leaflet and letter describing program and study (n = 1251)

- Excluded (n = 550)
  - Did not respond (n = 337)
  - Not interested (n = 213)

Expressed interest in participating & Assessed for eligibility (n = 701)

- Excluded (n = 623)
  - Too active (n = 330)
  - Receiving physical therapy (n = 150)
  - Poor health/Limited mobility (n = 129)
  - Scheduling/transport conflicts (n = 14)

Randomized (n = 78)

Allocated to Education Group & Received Education (n = 40)

- Analyzed (n = 40)
  - Lost to Follow-up (n = 4)
    - No reason given (n = 2)
    - Questionnaire too long (n = 2)

  - Analyzed (n = 36)

Allocated to MI + SR Group & Received MI+SR (n = 38)

- Dropped out of study Did not attend MI session (n = 2)

  - Analyzed (n = 36)
  - Lost to Follow-up (n = 5)
    - No reason given (n = 4)
    - Questionnaire too long (n = 1)

  - Analyzed (n = 31)
Table 1. Session-by-session description of intervention content using CALO-RE taxonomy of behavior change techniques*

<table>
<thead>
<tr>
<th>Behavior Change Technique</th>
<th>BCT #</th>
<th>Session 1 (GPES)</th>
<th>Session 2 (MI)</th>
<th>Session 3 (SRC 1)</th>
<th>Session 4 (SRC 2)</th>
<th>Session 5 (TFU 1)</th>
<th>Session 6 (TFU 2)</th>
<th>Session 7 (TFU 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provide information on consequences of behavior in general</td>
<td>1</td>
<td>✔</td>
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<tr>
<td>Provide information on consequences of behavior to the individual</td>
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<tr>
<td>Provide information on where and when to perform the behavior</td>
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<tr>
<td>Provide instruction on how to perform the behavior</td>
<td>21</td>
<td></td>
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<tr>
<td>Facilitate social comparisons</td>
<td>28</td>
<td>✔</td>
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<td>✔</td>
<td>✔</td>
<td>✔</td>
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<td>Motivational interviewing</td>
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<tr>
<td>Prompting focus on past success</td>
<td>18</td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
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<tr>
<td>Prompt self-monitoring of behavior</td>
<td>16</td>
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<tr>
<td>Goal setting (outcome goal)</td>
<td>6</td>
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<td>✔</td>
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<tr>
<td>Goal setting (behavioral goal)</td>
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<tr>
<td>Action planning</td>
<td>7</td>
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<tr>
<td>Set graded tasks</td>
<td>9</td>
<td></td>
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<tr>
<td>Prompt review of outcome goals</td>
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<tr>
<td>Provide feedback on performance</td>
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<tr>
<td>Behavior Change Technique</td>
<td>BCT #</td>
<td>Session 1 (GPES)</td>
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<td>Session 5 (TFU 1)</td>
<td>Session 6 (TFU 2)</td>
<td>Session 7 (TFU 3)</td>
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<tr>
<td>Teach to use prompts or cues</td>
<td>23</td>
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<tr>
<td>Barrier identification or problem solving</td>
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<td>Relapse prevention or coping planning</td>
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<td>Prompt review of behavioral goals</td>
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<tr>
<td>Prompt rewards contingent on effort or progress towards behavior</td>
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<tr>
<td>Plan social support or social change</td>
<td>29</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
<td></td>
</tr>
<tr>
<td>Use of follow-up prompts</td>
<td>27</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
</tbody>
</table>

* BCT # = Behavior change technique number taken from CALO-RE taxonomy of behavior change techniques [50]; GPES = Group patient education session, led by physical therapist and took place in week one of the intervention; MI = Motivational interview, delivered by different physical therapist and took place in either week 2 or week 3 depending upon scheduling availability; SRC = Self-regulation coaching sessions, led by rheumatology nurse practitioner and took place in week 4 and week 5 of the intervention; TFU = Telephone follow-up contacts, conducted by same rheumatology nurse practitioner in weeks 6, 12 and 18 of the intervention.
Table 2. Baseline characteristics of control and intervention groups*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention (n = 38)</th>
<th>Control (n = 40)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>60.7 ± 11.9</td>
<td>64.7 ± 11.5</td>
<td>.141</td>
</tr>
<tr>
<td>Women, n (%)</td>
<td>30 (79%)</td>
<td>22 (55%)</td>
<td>.024</td>
</tr>
<tr>
<td>Body Mass Index</td>
<td>27.7 ± 4.3</td>
<td>26.3 ± 3.6</td>
<td>.122</td>
</tr>
<tr>
<td>Employed, n (%)</td>
<td>13 (34%)</td>
<td>9 (23%)</td>
<td>.128</td>
</tr>
<tr>
<td>Primary, n (%)</td>
<td>18 (47%)</td>
<td>16 (42%)</td>
<td>.645</td>
</tr>
<tr>
<td>Secondary, n (%)</td>
<td>14 (37%)</td>
<td>15 (40%)</td>
<td>.813</td>
</tr>
<tr>
<td>Tertiary, n (%)</td>
<td>6 (16%)</td>
<td>7 (18%)</td>
<td>.761</td>
</tr>
<tr>
<td>NSAID use, n (%)</td>
<td>24 (63%)</td>
<td>21 (53%)</td>
<td>.347</td>
</tr>
<tr>
<td>Disease Activity, RADAI (0-10)</td>
<td>2.86 ± 1.74</td>
<td>3.87 ± 2.03</td>
<td>.021</td>
</tr>
<tr>
<td>Functional Status, HAQ (0-3)</td>
<td>0.98 ± 0.73</td>
<td>1.25 ± 0.59</td>
<td>.078</td>
</tr>
</tbody>
</table>

* Values are presented as mean ± standard deviation unless otherwise indicated; NS = non-significant; NSAID = Non-steroidal anti-inflammatory drugs; RADAI = Rheumatoid Arthritis Disease Activity Index; HAQ = Health Assessment Questionnaire.
Table 3. Main Group x Time intervention effects and between- and within-groups comparisons on primary and secondary outcomes at baseline, post-treatment, and follow-up with last observation carried forward for missing data (intention to treat dataset)*

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention Group (n = 38)</th>
<th>Control Group (n = 40)</th>
<th>Main Effect†</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>6 Weeks</td>
<td>32 Weeks</td>
</tr>
<tr>
<td>Self-efficacy for PA</td>
<td>78.1 ± 44.9</td>
<td>92.8 ± 37.7 §</td>
<td>92.8 ± 37.7 §</td>
</tr>
<tr>
<td>Autonomous Motivation</td>
<td>5.9 ± 0.8 ‡</td>
<td>6.0 ± 0.8</td>
<td>6.1 ± 0.7 §</td>
</tr>
<tr>
<td>Min/Week Leisure Time PA</td>
<td>216 ± 175</td>
<td>295 ± 204 §</td>
<td>303 ± 294 §</td>
</tr>
<tr>
<td>Days/Week ≥ 30 min PA</td>
<td>2.7 ± 1.2</td>
<td>4.6 ± 1.5 §</td>
<td>4.3 ± 1.6 §</td>
</tr>
<tr>
<td>Disease Activity, RADAI</td>
<td>2.9 ± 1.7 ‡</td>
<td>3.1 ± 1.7</td>
<td>3.2 ± 1.8</td>
</tr>
<tr>
<td>Functional Status, HAQ</td>
<td>0.98 ± 0.73</td>
<td>0.99 ± 0.70</td>
<td>0.99 ± 0.72</td>
</tr>
<tr>
<td>Depressive Symptoms, BSI</td>
<td>0.33 ± 0.46</td>
<td>0.26 ± 0.41 §</td>
<td>0.22 ± 0.36 §</td>
</tr>
<tr>
<td>Total Fatigue, CIS-20</td>
<td>67.1 ± 24.8</td>
<td>62.5 ± 22.9 §</td>
<td>62.7 ± 24.2</td>
</tr>
</tbody>
</table>

* Values are the mean ± SD unless otherwise indicated; \(\eta^2_{\text{partial}}\) = Partial eta-squared effect size; PA = Physical activity; RADAI = Rheumatoid Arthritis Disease Activity Index; HAQ = Health Assessment Questionnaire; BSI = Brief Symptom Inventory; CIS = Checklist of Individual Strengths.

† Main effects of group x time interaction based on repeated measures mixed ANOVAs adjusted for age, gender, and baseline level of disease activity.

§ Value differs significantly from baseline value (P_{within} < 0.05).

‡ Value differs significantly from control group at baseline (P_{between} < 0.05).
Table 4. Percentage of patients in each group meeting the 5 x 30 recommendations for physical activity.

<table>
<thead>
<tr>
<th>Time</th>
<th>MI + SR group</th>
<th>Education group</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>0/38 (0%)</td>
<td>0/40 (0%)</td>
<td>-</td>
</tr>
<tr>
<td>6 weeks</td>
<td>24/36 (67%)</td>
<td>9/39 (23%)</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>32 weeks</td>
<td>15/31 (48%)</td>
<td>9/36 (25%)</td>
<td>.046</td>
</tr>
</tbody>
</table>
References

Chapter 4


A Self-regulation Intervention to Increase Physical Activity


