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a randomised controlled trial

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CONCISE REPORT

The efficacy of motivational counselling and SMS reminders on daily sitting time in patients with rheumatoid arthritis: a randomised controlled trial

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ABSTRACT

Objectives The aim of this report is to investigate the efficacy of an individually tailored, theory-based behavioural intervention for reducing daily sitting time, pain and fatigue, as well as improving health-related quality of life, general self-efficacy, physical function and cardiometabolic biomarkers in patients with rheumatoid arthritis (RA).

Methods In this randomised controlled trial 150 patients with RA were randomised to an intervention or a no-intervention control group. The intervention group received three individual motivational counselling sessions and short message service or text messages aimed at reduction of sedentary behaviour during the 16-week intervention period. Primary outcome was change in daily sitting time measured objectively by ActiPVaL. Secondary outcomes included change in pain, fatigue, physical function, general self-efficacy, quality of life, blood pressure, blood lipids, haemoglobin A1c, body weight, body mass index, waist circumference and waist–hip ratio.

Results 75 patients were allocated to each group. Mean reduction in daily sitting time was –1.61 hours/day in the intervention group compared with 0.59 hours/day increase in the control group between-group difference –2.20 (95% CI –2.72 to –1.69; p<0.0001) hours/day in favour of the intervention group. Most of the secondary outcomes were also in favour of the intervention.

Conclusion An individually tailored, behavioural intervention reduced daily sitting time in patients with RA and improved patient-reported outcomes and cardiometabolic biomarkers.

Trial registration number NCT01969604; Results.

INTRODUCTION

Rheumatoid arthritis (RA) causes disability1 and barriers for exercise.2 Patients with RA have a 50%–60% increased risk of premature death from cardiovascular disease.3 Supplementary to the pharmacological treatment, patients are recommended to engage in moderate-to-vigorous physical activity.4 5 Most patients do not meet recommended levels of moderate-to-vigorous physical activity6 and 71%–92% of waking hours are spent sedentarily.7 Sedentary behaviour is defined as sitting or reclining while awake and with low-energy expenditure.8 In patients with chronic disease and mobility limitations, replacing sedentary behaviour with light intensity activities may prove more achievable than solely focusing on increasing moderate-to-vigorous physical activity.9 10 Studies have shown that reduction of daily sitting time through intervention is possible.11 12 Also, improved resting blood pressure, insulin levels and plasma glucose following regular interruptions of prolonged sitting have been reported.13 We aimed to investigate the efficacy of an individually tailored, theory-based behavioural intervention for reducing daily sitting time, pain and fatigue, as well as improving quality of life, general self-efficacy, physical function and cardiometabolic biomarkers in patients with RA.

METHODS

We performed an observer-blinded randomised controlled trial. The protocol was reported to the Danish Data Protection Agency (7111-08), approved by the Ethics Committee of the Capital Region of Denmark (H-2-2012-112) and registered at www.clinicaltrials.gov (NCT01969604). The Danish National Board of Health Biological Therapies (DANBIO) database,14 was searched for potential participants. A detailed description of the methods of the trial has previously been published. See protocol and feasibility paper.15 16

Patients were randomised 1:1 to intervention (n=75) or control group (n=75) by computer generated random numbers in blocks of 10. Participants and project staff delivering the intervention were unblinded to the participants’ allocation status, whereas outcome assessors and the statistician were blinded to allocation. The 16-week individually tailored, behavioural intervention consisted of three motivational counselling sessions conducted by health professionals and individual short message service (SMS) or text messages aiming to increase light intensity physical activity through reduction of sedentary behaviour. Participants randomised to the control group were instructed to maintain their current level of physical activity. We performed an observer-blinded randomised controlled trial. The protocol was reported to the Danish Data Protection Agency (7111-08), approved by the Ethics Committee of the Capital Region of Denmark (H-2-2012-112) and registered at www.clinicaltrials.gov (NCT01969604). The Danish National Board of Health Biological Therapies (DANBIO) database,14 was searched for potential participants. A detailed description of the methods of the trial has previously been published. See protocol and feasibility paper.15 16

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The primary outcome measure was change in daily sitting time measured by an ActiPVaL 3TM V.7.2.3 Activity Monitor (PAL Technologies, Glasgow, UK). The ActiPVaL uses accelerometer-derived information to determine time spent sitting/lying, standing and stepping and is validated in patients with RA.17 The participants wore the
monitor 24 hours per day for 7 days at baseline and by end of intervention, and recorded their daily sleeping time to separate sleep from waking sitting/lying time.

Secondary outcomes were changes from baseline to 16 weeks in self-reported daily sitting time at work and during leisure time and number of interruptions (‘breaks’) in daily sitting time, pain, fatigue physical function, quality of life (QoL) and general self-efficacy.¹⁵ Height was measured at baseline. Body weight, hip and waist circumference were additionally measured after 16-week intervention and body mass index (BMI, kg/m²) and had SMS reminders.

The intervention group had higher scores on fatigue, pain, had more daily sitting time and self-reported leisure-time sitting time than the control group (9.8 vs 8.8 hours and 5.3 vs 4.3 hours, respectively) (online supplementary table S1). All in the intervention group completed the counselling sessions (30–90 min) and had SMS reminders.

**RESULTS**

**Participants**

One thousand and eight patients were screened via DANBIO, hereof 801 (79%) were invited. Telephone-based screening was conducted with 722 of these, hereof 617 (85%) were eligible. Of these, 467 declined to participate (online supplementary figure S1). Compared with those declining participation, the included patients were older (60 vs 52 years), had longer disease duration (15 vs 12 years), lower Health Assessment Questionnaire (HAQ) (0.7 vs 1.1) and more were women (81% vs 69%). Outcomes were obtained for 147 (98%) of the randomised patients.

The intervention group had higher scores on fatigue, pain, had more daily sitting time and self-reported leisure-time sitting time than the control group (9.8 vs 8.8 hours and 5.3 vs 4.3 hours, respectively) (online supplementary table S1). All in the intervention group completed the counselling sessions (30–90 min) and had SMS reminders.

**Primary outcome**

Reductions in daily sitting time favoured the intervention group (online supplementary figure S2). Estimates of intervention effect for behavioural and patient-reported outcomes are presented in [table 1](#). Objectively measured daily sitting time decreased in intervention group by on average 1.61 hours/day and increased in control group by 0.59 hours/day. The difference in change between groups was statistically significant in favour of intervention group (−2.20 hours/day (95% CI −2.72 to −1.69)). The decrease in daily sitting time was replaced by increased standing time.

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**Table 1 Mean changes in behavioural and patient-reported outcomes after 16 weeks**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean change from baseline mean (95% CI)</th>
<th>Difference in change between groups mean (95% CI)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily sitting time (ActivPAL) hours/day</td>
<td>−1.61 (−1.97 to −1.25)</td>
<td>−2.20 (−2.72 to −1.69)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Daily standing time* (ActivPAL) hours/day</td>
<td>1.25 (0.82 to 1.68)</td>
<td>1.52 (1.10 to 1.95)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Daily stepping time* (ActivPAL) hours/day</td>
<td>0.50 (0.26 to 0.95)</td>
<td>0.55 (0.35 to 0.74)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Breaks up of daily sitting (ActivPAL) number/day</td>
<td>−0.47 (−3.52 to 2.57)</td>
<td>1.50 (−2.81 to 5.81)</td>
<td>0.49</td>
</tr>
<tr>
<td>Self-reported sitting time at work (hour/day)</td>
<td>−1.12 (−1.68 to −0.57)</td>
<td>−1.13 (−1.90 to −0.35)</td>
<td>0.005</td>
</tr>
<tr>
<td>Self-reported sitting time in leisure (hour/day)</td>
<td>−1.30 (−1.68 to −0.93)</td>
<td>−1.46 (−2.00 to −0.92)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Physical function (HAQ)</td>
<td>−0.28 (−0.36 to −0.19)</td>
<td>−0.42 (−0.54 to −0.30)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Fatigue (VAS)/mm</td>
<td>−19.04 (−24.22 to −13.86)</td>
<td>−26.80 (−34.32 to −19.30)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Fatigue (MFI)</td>
<td>−2.17 (−3.00 to −1.35)</td>
<td>−3.43 (−4.59 to −2.26)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Physical fatigue</td>
<td>−3.18 (−4.02 to −2.34)</td>
<td>−4.52 (−5.73 to −3.30)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Mental fatigue</td>
<td>−1.80 (−2.50 to −1.10)</td>
<td>−2.46 (−3.46 to −1.46)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Reduced activity</td>
<td>−3.28 (−4.05 to −2.50)</td>
<td>−4.88 (−5.99 to −3.77)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Reduced motivation</td>
<td>−1.35 (−2.00 to −0.69)</td>
<td>−2.60 (−3.54 to −1.67)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Pain (VAS)/mm</td>
<td>−14.77 (−19.50 to −10.04)</td>
<td>−22.36 (−29.27 to −15.44)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Self-efficacy (GSES)</td>
<td>3.96 (2.80 to 5.12)</td>
<td>6.21 (4.54 to 7.88)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>HR-QoL (SF-36)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SF36-PCS</td>
<td>6.30 (4.33 to 8.26)</td>
<td>8.88 (6.06 to 11.69)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>SF36-MCS</td>
<td>4.94 (3.42 to 6.46)</td>
<td>6.77 (4.62 to 8.92)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

* Not an outcome measure, however, changes in daily sitting, standing and/or stepping time are interdependent, and reduced sitting time may be replaced by either standing or stepping time.

GSES, General Self-efficacy Scale; HAQ, Health Assessment Questionnaire; HR-QoL, Health-Related Quality of Life; MCS, Mental Component Scale; MFI, Multidimensional Fatigue Inventory; PCS, Physical Component Scale; SF36, 36-Item Short Form Survey Instrument; VAS, Visual Analogue Scale.
and stepping time with between-group differences in change of 1.52 hours/day and 0.53 hours/day, respectively.

**Secondary outcomes**

Statistically significant differences in favour of the intervention group were found in self-reported daily sitting time at work and during leisure time, for fatigue, pain, physical function, QoL, general self-efficacy and in total cholesterol (tables 1 and 2); also significantly greater proportions achieved clinically meaningful improvements in physical function (HAQ) (minimal clinically important difference (MCID)=0.22), fatigue (Visual Analogue Scale) (MCID=10 mm) and pain (MCID=10 mm) (table 2).²⁹

For anthropometric and cardiometabolic measures, no statistically significant differences were found, but numerical differences in change were all in favour of intervention group (table 3).

**DISCUSSION**

Individual motivational counselling sessions during a 16-week period accompanied by individual SMS reminders reduced daily sitting time by more than 2 hours compared with the control group. Patient-reported outcomes also improved and, to a lesser extent, cardiometabolic biomarkers. Patients with RA need to manage consequences of an unpredictable disease every day, why the intervention was individualised and targeted sedentary behaviour. This whole-day approach was also targeted in a why the intervention was individualised and targeted sedentary behaviour. This whole-day approach was also targeted in a

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean change from baseline, mean (95% CI)</th>
<th>Difference in change between groups, mean (95% CI)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (kg)</td>
<td>0.00 (−0.91 to 0.92)</td>
<td>0.58 (−0.34 to 1.49)</td>
<td>−0.58 (−1.87 to 0.72)</td>
</tr>
<tr>
<td>Waist circumference (cm)</td>
<td>−0.80 (−1.90 to 0.30)</td>
<td>0.71 (−0.39 to 1.81)</td>
<td>−1.51 (−3.07 to 0.05)</td>
</tr>
<tr>
<td>Waist–hip ratio</td>
<td>−3.03 (−4.72 to 1.35)</td>
<td>−1.81 (−3.50 to −0.13)</td>
<td>−1.22 (−3.60 to 1.16)</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>0.02 (−0.30 to 0.32)</td>
<td>0.16 (−0.17 to 0.49)</td>
<td>−0.14 (−0.60 to 0.28)</td>
</tr>
<tr>
<td>Blood pressure (mm Hg)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic</td>
<td>−3.06 (−5.98 to −0.14)</td>
<td>−1.57 (−4.49 to 1.34)</td>
<td>−1.49 (−5.61 to 2.64)</td>
</tr>
<tr>
<td>Diastolic</td>
<td>−0.85 (−2.38 to 0.69)</td>
<td>−0.08 (−1.62 to 1.45)</td>
<td>−0.77 (−2.94 to 1.40)</td>
</tr>
<tr>
<td>Lipids (mmol/L)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cholesterol</td>
<td>−0.24 (−0.33 to −0.14)</td>
<td>0.13 (0.04 to 0.23)</td>
<td>−0.37 (−0.50 to −0.24)</td>
</tr>
<tr>
<td>HDL</td>
<td>0.06 (0.00 to 0.12)</td>
<td>0.00 (−0.06 to 0.05)</td>
<td>0.07 (−0.01 to 0.14)</td>
</tr>
<tr>
<td>LDL</td>
<td>−0.07 (−0.18 to 0.04)</td>
<td>−0.03 (−0.13 to 0.08)</td>
<td>−0.04 (−0.20 to 0.11)</td>
</tr>
<tr>
<td>Triglyceride</td>
<td>0.06 (−0.06 to 0.18)</td>
<td>0.06 (−0.06 to 0.17)</td>
<td>0.00 (−0.16 to 0.17)</td>
</tr>
<tr>
<td>HbA1c (mmol/mol)</td>
<td>−0.05 (−0.22 to 0.12)</td>
<td>0.10 (−0.07 to 0.27)</td>
<td>−0.15 (−0.40 to 0.09)</td>
</tr>
</tbody>
</table>

The results may not be generalisable to all patients with RA, since those how declined participation were younger and the proportion of men was higher. The intervention may have been more appealing to women, since 81% of the included patients were women; however, up to 75% of patients with RA are women.³⁰ It is also noteworthy that participants were older and had longer disease duration than non-participants. Focus on light everyday activities and individual tailoring may be particular appealing to this group of patients. Only three participants

**Table 2** Proportions of participants achieving clinically important improvements in physical function, fatigue and pain with corresponding risk differences

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention group</th>
<th>Control group</th>
<th>Risk difference (95% CI)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Achieved 0.22 improvement in HAQ scores</td>
<td>38 (51)</td>
<td>4 (5)</td>
<td>46% (33% to 58%)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Achieved 10 mm improvement on VAS for fatigue</td>
<td>46 (62)</td>
<td>10 (14)</td>
<td>48% (35% to 62%)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Achieved 10 mm improvement on VAS for pain</td>
<td>47 (64)</td>
<td>9 (12)</td>
<td>51% (38% to 64%)</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

HAQ, Health Assessment Questionnaire; VAS, Visual Analogue Scale.
(2%) dropped out at end of intervention, which underlines the acceptability of the individually tailored intervention allowing them to set achievable goals for change in everyday activities.

In conclusion, a randomised, observer-blinded 16-week individually tailored, theory-based behavioural intervention with motivational counselling and SMS reminders reduced daily sitting time by an average of 2 hours, improved general self-efficacy, QoL, physical function, total cholesterol and reduced levels of pain and fatigue in sedentary patients with RA.

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8 Musculoskeletal Statistics Unit, The Parker Institute, Copenhagen University Hospital, Bispebjerg and Frederiksberg, Copenhagen, Denmark
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Contributors BAE, JM, MA, NB, MLH, KL, MO, PU and TT designed and planned the trial in collaboration with the trial steering committee. BAE, KL and TT obtained funding. TT managed the day-to-day running of the trial. RC designed the statistical analysis plan and carried out the data analyses in collaboration with TT. MA advised on the analyses and interpretations of ActivPAL data. All authors had full access to the data and take responsibility for the integrity of the data and for the accuracy of the data analysis. Additionally, all authors contributed to the interpretation of the results and reviewed and approved the final manuscript. TT drafted this article and is the guarantor.

Competing interests None declared.

Patient consent Obtained.

Ethics approval Danish Data Protection Agency (711-1-08) and the Ethics Committee of the Capital Region of Denmark (H-Z-2012-112).

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement BAE is willing to examine all requests for the full dataset after a period of 5 years from the date of this publication. The trial steering committee will be involved in the case of query about access to data. Participants did not give consent for data sharing but the presented data are anonymised and risk of identification is low.

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