RMD Open
Rheumatic & Musculoskeletal Diseases

ORIGINAL RESEARCH

Cost-effectiveness of motivational counselling and text reminders in patients with rheumatoid arthritis: results based on a randomised clinical trial

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To cite: Sørensen J, Esbensen BA, Aadahl M, *et al*. Cost-effectiveness of motivational counselling and text reminders in patients with rheumatoid arthritis: results based on a randomised clinical trial. *RMD Open* 2022;**8**:e002304. doi:10.1136/rmdopen-2022-002304

► Additional supplemental material is published online only. To view, please visit the journal online (http://dx.doi.org/10.1136/rmdopen-2022-002304).

Received 23 February 2022
Accepted 18 May 2022

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ABSTRACT

Objective The aim of this study was to evaluate the cost-effectiveness of an individually tailored intervention consisting of motivational counselling and text message reminders to reduce sedentary behaviour in comparison with usual lifestyle in patients with rheumatoid arthritis (RA).

Methods RA patients (n=150) were randomised to the intervention or control group. Costs of the intervention and healthcare utilisation during a 22-month follow-up period were reported. Outcomes were objectively measured as 24 hours/7 days sitting time and self-reported Health Assessment Questionnaire (HAQ) and EQ-5D scores at baseline, and 16 weeks, 10 and 22 months after baseline. Cost-effectiveness was reported as incremental cost-effectiveness ratios and statistical uncertainty presented as cost-effectiveness acceptability curves.

Results The intervention cost was estimated at €387 per participant. The mean incremental 22-month healthcare cost was €−1165 (95% bootstrap CI −5613 to 3283). An incremental 20%-point of the participants (CI 10.4% to 29.6%) reduced their daily sitting time more than 50 min and 36%-point reported better HAQ scores (change>0.22). The time-weighted health utilities (quality-adjusted life years (QALYs)) increased by 0.10 (CI 0.02 to 0.18) and 0.11 (CI 0.04 to 0.19) for EQ-5D index and EQ-VAS, respectively. The intervention dominated usual lifestyle by offering better outcomes and lower costs. With a threshold value of €30 000/QALY the intervention has a probability of 95% of being cost-effective.

Conclusion This protocolised cost-effectiveness analysis showed that an individually tailored intervention aimed at reducing sedentary behaviour in patients with RA is improving participants' 22-month health status and reducing healthcare costs. These results suggest that the intervention should be implemented in routine rheumatology care.

Trial registration number NCT01969604.Trial registration number

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ There are substantial behavioural changes, reduced daily sitting time and improved cardiometabolic biomarkers from an intervention of motivational counselling and text message reminders compared with usual lifestyle in patients with rheumatoid arthritis (RA).

WHAT THIS STUDY ADDS

⇒ The cost of the intervention is relatively modest, and this analysis suggests that the intervention is dominating usual lifestyle and is with 95% probability cost-effective at a threshold value of €30 000 per quality-adjusted life year.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE AND/OR POLICY

⇒ Based on the results from this analysis, further work should be done to implement individual physical activity guidance and the principles of motivational counselling and text message reminders into routine clinical practice. In addition, there is a need to explore the value for money by offering the intervention to patients with RA with different characteristics, health status, lifestyle and motivation.

INTRODUCTION

Recent EULAR recommendations[1] acknowledge that regular physical activity and exercise in patients with rheumatoid arthritis (RA) is effective and safe at reducing fatigue and pain,[2 3] improving aerobic capacity[2 4] and physical function.[2 5] However, patients with RA appear to be less physically active than the general population[6 7] with up to 80% not engaging in regular weekly exercise,[7] and spending 90%–95% of their daily time awake with sedentary behaviours[8 9] compared with 60%–70% of the general population.[10] Barriers to physical activity can relate to older age, comorbidity, low functional capacity and higher levels of fatigue and pain.[7] Behavioural approaches such as patient education and individual counselling focusing on the patients' motivation, self-efficacy and

overcoming individual barriers to physical activity may have positive effect on physical activity adherence.[11]

The 'Joint Resources—Sedentary Behaviour' (JR-SB) trial applied a behavioural approach to reduce daily sitting time and increase light-intensity physical activity in patients with RA.[12] In a randomised controlled trial, individual motivational counselling and text message reminders aimed at reducing sedentary behaviour and increase daily standing, moving and stepping time in patients with RA. The primary results showed significant between-group differences on behavioural, patient-reported and cardiometabolic outcomes both after 4 months and 22 months after baseline.[13 14] Based on the long-lasting impact of the intervention on physical activity behaviour and health, these results point to the prospect of scaling up the intervention in rheumatology routine care for the health benefits of a wider population of patients with RA. In addition, it may provide a rationale and aid the decision to implement the intervention in routine clinical practice with evidence to suggest that the intervention provided health benefits at an acceptable cost. To date, only few studies have reported cost-effectiveness analyses comparing the costs and health benefits of physical activity interventions for patients with RA,[15 16] although these complementary analyses seem to be increasingly premeditated.[17]

The aim of the present study was to evaluate the cost-effectiveness of the individually tailored, behavioural intervention in the JR-SB trial compared with usual lifestyle in patients with RA. This included a comparison of the intervention costs with the proportion of participants, who during the 22-month follow-up period, reduced their daily sitting time, improved their physical function and achieved improvements in health-related quality of life (HRQoL) and quality-adjusted life years (QALYs).

METHODS

The cost-effectiveness analysis (CEA) was conducted from a regional healthcare funder perspective in accordance with international guidelines for economic evaluations alongside clinical trials[18 19] and reported according to international standards[20] and adhering to current Danish guidelines.[21] The study used data from the JR-SB trial. The trial design, patient recruitment, data collection procedures and the primary analysis of clinical outcomes have been reported previously.[13 14 22]

The JR-SB trial

Briefly, 150 patients aged over 18 years, diagnosed with RA (meeting the ACR classification criteria for RA) for more than 1 year, with a current Health Assessment Questionnaire (HAQ) score[23] of less than 2.5, access to a mobile phone, good comprehension of Danish language, with more than 5 hours of self-reported daily sitting time and with no more than 8 weekly hours of vigorous physical activity participated in the trial.[19] The cohort of participants was recruited from a telephone screening of 722 of 801 potentially eligible participants identified through the DANBIO clinical database.[14] In total, 467 declined to participate and 105 did not fulfil the inclusion criteria. Overall, 150 consented to be randomised to the 16-week intervention and received 3 individual motivational counselling sessions (30–90 min) and 1–5 weekly, individualised text messages reminding them of their behavioural goals about reducing daily sitting time. Participants in the control group (CG) were encouraged to maintain their usual lifestyle. Further details of the recruitment and intervention have been previously published.[12] The recruitment of participants began in March 2013 and by May 2016 the last participant had completed the 22-month follow-up. The baseline characteristics of participants have been reported previously[14] and are summarised in table 1. At baseline, the intervention group (IG) had higher mean scores on fatigue and pain, more daily sitting time and worse HAQ score.

Resource use and costs

The intervention cost was assessed based on the full financial accounts of the trial recorded by the hospital's Financial Department and the Principal Investigator's Excel sheet of all committed expenditures. Each expenditure was categorised as costs related to either the intervention or activities related to planning and conducting the trial. Only costs related to the intervention were included here. The detailed analysis of the intervention cost is available as online supplemental material 1.

The time cost of the healthcare professionals (HCPs) delivering the intervention (motivational counselling sessions) was based on the average gross salary paid to a mid-range nurse (€5500) for an effective working month of 94 hours per month.[21] The hourly cost equates to €59 per hour. The time use for providing the intervention was assumed as the face-to-face contact time with addition of preparation time related to each contact/session. The intervention included an initial counselling session of 1.5 hours duration and two subsequent sessions of 1-hour duration provided by HCPs, that is, 3.5 hours. The cost of HCP face-to-face sessions was assumed at 3.5 hours × €59 per hour (€205 per patient) with addition of a 40% staff-related overhead[21] (€82), in total €287 per participant.

Crucial for the intervention was a system to send encouraging text messages to participants several times per week during the 16-week intervention period. This tailor-made system was developed by independent developers who were paid an agreed fee, which was included in the intervention expenditures. As the system was automated, the marginal cost per additional participant was negligible within a defined group size and considered a sunk cost. In addition to the system development, individually formulated text messages were sent to participants. The management and application of the text messaging system was assumed to take an hour of staff time per participant during the whole intervention. This equates to an assumed cost at €80 per participant.

Table 1 Characteristics of participants and their baseline scores and healthcare cost (3 months prior), physical and health status measures

	Intervention group (n=75) (%/SD)	Control group (n=75) (%/SD)	P value
Sex (n, %)			
Males	14 (19)	15 (20)	0.836
Females	61 (81)	60 (80)	
Age (mean, SD)	59.7 (10.7)	59.5 (12.7)	0.895
Living arrangement (n, %)			
Living alone	22 (29)	24 (32)	0.723
Living with partner	53 (71)	51 (68)	
Education (n, %)			
Basic schooling	10 (13)	11 (15)	0.838
Vocational training	19 (25)	19 (25)	
Shorter education	14.0 (19)	10.0 (13.3)	
Longer education	32 (43)	35 (47)	
BMI (mean, SD)	26.1 (5.5)	26.8 (5.3)	0.402
Years with RA (mean, SD)	15.2 (11.0)	14.7 (11.3)	0.759
Healthcare costs (€) (mean, SD)	1896 (7639)	1250 (3039)	0.497
Daily sitting time (h) (mean, SD)	9.9 (1.9)	8.8 (1.7)	0.001
Daily interruptions in sitting time (n) (mean, SD)	52.8 (14.2)	55.6 (16.9)	0.277
Sitting at work (min) (n=67) (mean, SD)	256 (140)	256 (148)	0.997
Sitting at leisure (min) (mean, SD)	314 (141)	263 (124)	0.021
HAQ Score (mean, SD)	0.9 (0.6)	0.6 (0.6)	0.003
EQ-5D (mean, SD)	0.793 (0.187)	0.822 (0.179)	0.329
EQ-VAS (mean, SD)	62.9 (20.1)	68.5 (18.6)	0.075

BMI, body mass index; HAQ, Health Assessment Questionnaire; RA, rheumatoid arthritis.

Staff training in motivational interviewing principles and techniques was provided by a psychologist before the start of the trial and included a full day of initial training and two half-days subsequent training. The cost of the training programme included development of teaching material, planning of the training programme and the fee paid to the trainer. In addition, rent of the training facilities, coffee and lunch accounted for €30 per participant per day. Based on these assumptions, the staff training cost was assumed at €500 per participating staff. This cost could be considered as a sunk cost, although if the programme is to be implemented in routine care, there will be a need for ongoing training of new staff. The training cost of €20 per participant was added to the intervention cost.

The recruitment of participants was assumed to relate to the conduct of the clinical trial. Recruitment was done by one of the investigators (TT). It included a written invitation sent to patients routinely attending the outpatient clinic and identified in the DANBIO database as eligible according to inclusion criteria. A personal conversation was held to inform patients about the trial and was assumed to last about 15 min. The actual number of contacted patients was recorded, and the recruitment cost thus consisted of postage of written material and staff time.

Other healthcare costs

The use of other healthcare resources during the 22-month follow-up period was obtained from the national health registries through 'Sundhedsdatastyrelsen' (The Danish Health Data Authority) using scrambled person identifiers. The use of primary and secondary healthcare resources during the follow-up period was extracted based on the individual participant's date of inclusion into the trial. The use of healthcare resources during a 3-month period prior to trial inclusion was also extracted. Activities in primary care were categorised as: general practice (GP), physiotherapy, privately practicing medical specialists, dentists and other primary care providers. Secondary care was categorised as outpatient visits and inpatient hospital admissions.

The reported fees for primary care services were interpreted to reflect the full healthcare cost from the regional health authority's perspective.[21] Similarly, the diagnostic related group costs for outpatient and inpatients were used as complete cost measures.[21] All costs were uplifted to 2020 values using the consumer price index

published by Statistics Denmark. To account for different timing of the resource use, the net present value (NPV) was calculated using monthly discounting based on the 3.5% annual discount rate recommended by the Danish Ministry of Finance.[24] The accumulated NPV costs were converted into € (1€=7.45 Danish kroner).

Effectiveness

From the JR-SB trial, validated data on daily sitting time, physical function (HAQ score) and HRQoL (EQ-5D health utility scores) were available at baseline, 16 weeks, 10 months and 22 months after baseline, respectively. Daily sitting time was measured using an ActivePAL 3TM monitor worn by the participant in a 7-day period at each assessment point.[13] A clinically important change in daily sitting time was assumed at 50 min.[12 25]

The HAQ and EQ-5D scores were obtained through questionnaires at each assessment time. HAQ is an instrument measuring physical function that can be combined into a score ranging 0–3, where a low score indicates few functional limitations.[23] The minimal clinical important difference has been identified as a score change of 0.22.[26 27] The EQ-5D is a generic measure of health status widely recommended for outcome measurements in economic evaluations.[28] In this study, the Danish 5-level version was used.[29 30] The recently developed Danish scoring algorithm was used to derive utility scores.[30 31] A score of 1 indicates full health while 0 indicates death. Negative scores indicate health states worse than death.

Statistical analysis

The analytical perspective of the effectiveness was objectively measured participant-specific daily sitting time (hours per day), participants' self-reported functional and health status, and registry-based data on use of healthcare services. The time perspective for the analysis was from inclusion in the trial until 22 months after. Costs were assigned from the perspective of the regional health authority.

The sample size was determined to identify a mean group difference in the primary outcome—daily sitting time—of 50 min with a significance level of 5% and power of 80% in an intention-to-treat population of 75 participant in each group.[12]

The analysis of outcomes and costs was conducted according to the intention-to-treat principle, which means that all randomised participants were analysed in their randomised group irrespective of compliance with the trial and data collection protocol.

Explorative analysis investigated group differences in cost and health status at each time point (online supplemental material 2). Significance levels from simple t-test for group mean differences assuming independent groups were reported. The registry resource use data were assumed to be complete for all participants during the whole observation period. The effect data points were available for most participants. In the calculation of differences in accumulated effects during the whole observation period replacements of missing observations used 'last observation carried forward'. More sophisticated multiple imputations methods were explored, but due to the nearly complete data set, the base case results were reported using the simpler replacement strategy. Time-weighted mean scores for each group were constructed for the proportion of participants with reduced daily sitting time (>50 min), work sitting time and leisure walking time, interruptions of daily sitting time and HAQ score. Time-weighted utility scores based on EQ-5D responses were interpreted as QALYs.

Mean group differences at each data point were estimated using multilevel regression analysis where the estimated parameters for the interaction of IG and observation time were interpreted as difference-in-difference estimates (online supplemental material 3). The mean group differences were estimated using seemingly unrelated regression with the interaction of the group variable as the primary effect parameters as recommended.[32 33] The model fit and precision improved with baseline adjustment and adjustment using three age categories (<50, 50–70, >70 years of age).

In the cost-effectiveness analysis (CEA), the total cost of the intervention and resource use of each individual participant was analysed in relation to different measures of effect—proportion with appropriate change in sitting time, change in functional status and HRQoL during the observation period.

As the mean incremental cost-effectiveness ratio was negative (ie, the intervention was cheaper and provided better outcomes), cost-effectiveness was presented as net monetary benefit (NMB) assuming a value of €30 000 per QALY. Bootstrap methods were used to explore the statistical uncertainties and cost-effectiveness acceptability curves used to illustrate the uncertainty in the 'value-for-money' assessment. As a means of testing the robustness of the results, a number of sensitivity analyses were conducted.[34] All analyses were conducted using Stata V.17. A value of $p<0.05$ was considered statistically significant.

RESULTS

Cost differences

The total cost of the intervention was €29 000 (2020 price level). The mean cost for the intervention was assumed at €387 per participant. This included the face-to-face staff cost, 40% overhead on staff cost, administration of the text messages during the 16-week intervention period, and a contribution for system development and staff training.

The 3-month mean healthcare cost prior to randomisation was €1896 (SD 7630) for participants in the IG and €1250 (SD 3038) for participants in the CG. The accumulated 22-month healthcare costs are shown in table 2 as €8824 for the IG and €9990 for the CG. The NPV was €8569 and €9663. The mean cost for the IG was €1165 (NPV €1095) lower than for the CG, although

Table 2 Mean accumulated healthcare costs 22 months after inclusion into the JR-SB trial (mean 2020-Euro; 95% bootstrap CI)

Cost related to	Intervention group	Control group	Difference
Intervention	387 (–)	0 (–)	387 (–)
General practice	300 (235 to 366)	346 (277 to 415)	−46 (−140 to 48)
Physiotherapy	776 (474 to 1078)	573 (316 to 829)	203 (−194 to 600)
Priv. medical specialist	288 (206 to 371)	244 (165 to 322)	45 (−71 to 161)
Dentist	95 (75 to 115)	114 (90 to 138)	−19 (−50 to 12)
Other primary care	78 (35 to 122)	57 (33 to 81)	21 (−29 to 71)
Hospital outpatient	4674 (2339 to 7010)	4562 (3065 to 6059)	112 (−2667 to 2891)
Hospital inpatient	2226 (413 to 4039)	4094 (1735 to 6453)	−1868 (−4864 to 1127)
Total cost	8824 (5712 to 11937)	9990 (6730 to 13249)	−1165 (−5613 to 3283)
NPV total cost	8569 (5647 to 11490)	9663 (6692 to 12635)	−1095 (−5273 to 3083)

JR-SB, Joint Resources—Sedentary Behaviour; NPV, Net present value.

the difference was not statistically significant. The IG had lower mean cost for hospital inpatient services, GP and dentist services and higher cost for hospital outpatient services, services provided by GP, primary care physiotherapists and medical specialists, although none of these differences were statistically significant.

Outcome differences

The difference in time-weighted daily sitting time and health status outcomes after 22 months are shown in table 3. A total of 21.3% of intervention participants reduced their daily sitting time by more than 50 min, while this was the case for only 1.3% of the participants in the CG. This indicates an incremental 20%-point higher proportion of participants in the IG (95% CI 10.4% to 29.6%) became more active during the 22-month observation period. For the 67 participants in the labour marked (from the total sample), an incremental 12%-point reduced their sitting time at work. A 45%-point higher proportion of participants in the IG increased their daily walking time. The proportions of more active participants in the IG were all statistically significant.

In addition to the reduction in daily sitting time, more than 36%-point of the participants reported better HAQ scores (>0.22). This was also reflected in the time-weighted health utility scores. Using the EQ-5D scores, the IG had an incremental gain of 0.10 QALYs during the observation period in comparison with the CG, and a slightly larger gain if measured by the EQ-VAS score. These incremental gains were all statistically significant.

Cost-effectiveness

Table 4 compares the incremental cost and incremental effect using different outcome measures. In contrast to the data in previous tables, these data have been adjusted for baseline scores and three age categories using seemingly unrelated regression to take account of the correlation between the measurement of costs and outcomes. All cost-effectiveness estimations suggest that the intervention dominates the CG by providing better outcomes at lower costs.

Figure 1 shows the cost-utility analysis using the EQ-5D outcome data. The scatter plot shows positive QALY gains with a broad spread in costs. The cost-effectiveness

Table 3 Time-weighted physical activity and health status outcomes 22 months after inclusion (mean and 95% bootstrap CI)

	Intervention group	Control group	Difference
Proportion with improved			
Daily sitting time (reduced by 50 min)	0.213 (0.121 to 0.306)	0.013 (−0.013 to 0.039)	0.200 (0.104 to 0.296)
Daily interruptions of sitting time	0.853 (0.773 to 0.933)	0.813 (0.725 to 0.902)	0.040 (−0.079 to 0.159)
Work sitting time (reduced by 50 min) (n=67)	0.213 (0.121 to 0.306)	0.093 (0.027 to 0.159)	0.120 (0.006 to 0.234)
Leisure sitting time	0.600 (0.489 to 0.711)	0.147 (0.067 to 0.227)	0.453 (0.317 to 0.590)
Proportion with improved			
Physical function (HAQ Score change>0.22)	0.373 (0.264 to 0.483)	0.013 (−0.013 to 0.039)	0.360 (0.247 to 0.473)
Time-weighted health status (QALYs)			
EQ-5D index	1.234 (1.189 to 1.279)	1.133 (1.068 to 1.198)	0.101 (0.022 to 0.181)
EQ-VAS	1.029 (0.981 to 1.078)	0.916 (0.858 to 0.974)	0.114 (0.037 to 0.190)

HAQ, Health Assessment Questionnaire; QALYs, quality-adjusted life years.

Table 4 Cost-effectiveness using different time-weighted physical activity and health status outcomes (mean and 95% bootstrap CI)

	Incremental cost (€)	Incremental effect	ICER (€ per unit effect)	Comment
Sitting time outcome				
Proportion with reduced sitting time (>50 min)	−737 (−5238 to 3764)	0.125 (0.044 to 0.206)	−5895	Intervention dominates
Physical function (HAQ score)				
Proportion with improved score (>0.22)	−734 (−5124 to 3655)	0.307 (0.197 to 0.416)	−2394	Intervention dominates
QALYs				
EQ-5D	−679 (−5071 to 3713)	0.122 (0.063 to 0.181)	−5585	Intervention dominates
EQ-VAS	−679 (−5345 to 3986)	0.149 (0.089 to 0.209)	−4560	Intervention dominates

Estimated using bootstrapped (n=1000) seemingly unrelated regression with adjustment for baseline score and three age categories.
HAQ, Health Assessment Questionnaire; ICER, incremental cost-effectiveness ratio; QALYs, quality-adjusted life years.

acceptability curve shows that at a zero-threshold value per QALY there is more than 50-50 chance that the intervention is cost-effective. At a threshold of €30 000 per QALY, the intervention is nearly 95% likely to be cost-effective.

The regression analysis aimed at identifying variations in NMB and participant characteristics did not provide any indications of particular patient characteristics with better or worse NMBs (baseline cost, sitting time, interruptions, sitting at work, sitting at leisure, baseline HAQ, EQ-5D index and EQ-VAS).

DISCUSSION

This protocolised CEA showed that over a 22-month observation period, the 16-week intervention with individually tailored motivational counselling and text message reminders in a group of patients with RA provided better

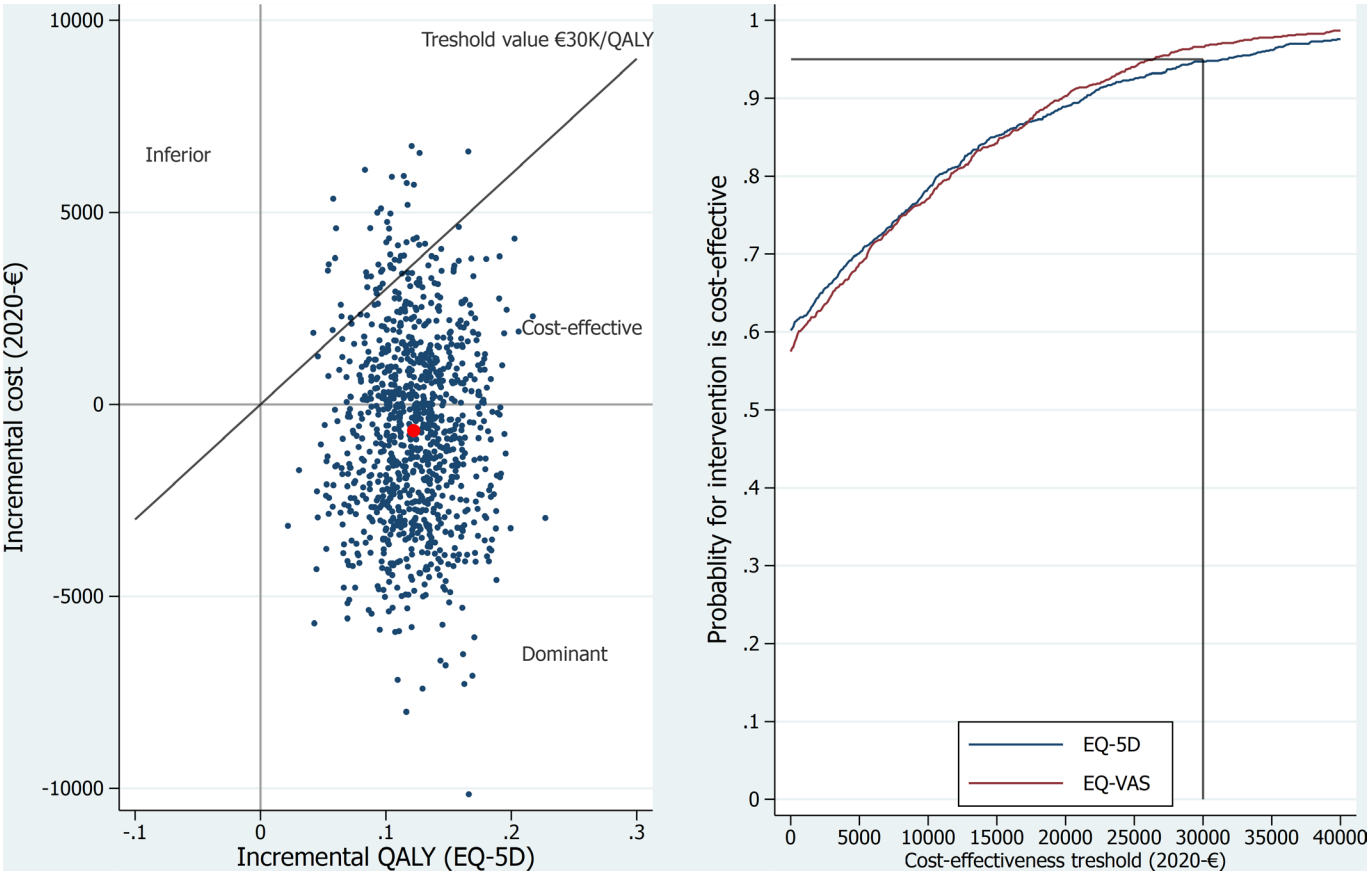

Figure 1 Scatterplot of 1000 bootstrap replications and cost-effectiveness acceptability curve using EQ-5D and EQ-VAS. QALY, quality-adjusted life year.

outcomes at cheaper costs in comparison with usual lifestyle. The change in physical activity behaviour was correlated with the long-term physical function as measured by the HAQ score and health utilities measured by EQ-5D and EQ-VAS. The cost of the intervention was relatively modest (€387 per participant), and the analysis suggested that the intervention is more than 95% likely to be cost-effective using a standard threshold value of €30 000 per QALY.

While it is essential to evaluate the economic benefits of exercise and physical activity interventions in patients with RA to inform future trials, possible implementation efforts and decision-makers, very few studies have conducted cost-effectiveness analyses. The previous RAPIT trial[35] tested the efficacy of a physiotherapist-led high-intensity intervention with 2 weekly weight-bearing exercise classes over a period of 2 years (n=300). The trial demonstrated improvements in functional ability (HAQ), physical capacity and bone mineral density in favour of the IG. However, the subsequent CEA[16] did not show that the intervention was cost-effective in comparison to standard physical therapy treatment. No incremental gains in health utility scores (QALYs based on EQ-5D and EQ-VAS data) were observed. This is different to the JR-SB trial, which showed statistically significant improvements in QALYs.

Also, the PARA trial[15 36] investigated the efficacy of a 1-year coaching programme, guided by physiotherapists, and based on the principles of graded activity training. Similar to the JR-SB trial, the information session and the monthly supportive telephone counselling included information on the benefits of physical activity, discussions on possibilities and problem-solving, and individual goal setting related to physical activity. While the trial (n=228) showed significant effect of the intervention on perceived health and muscle strength after 1 year, the subsequent cost-effectiveness analysis[15] concluded that the health improvements were not justified by the additional costs. However, the trial showed significant improvements in EQ-VAS and estimated incremental cost of an extra EQ-VAS point improvement at €116.[15]

The difference in cost-effectiveness between the JR-SB intervention and the two other interventions may largely be explained by the differences in intervention and study design. Both the RAPIT trial and the PARA trial included multiple in-clinic consultations with physiotherapists over a 1-year[15] and 2-year[16] period, respectively. These long-term interventions had high costs at €716[15] and €780[16] per participant, compared with €387 per participant in the JR-SB intervention. The JR-SB intervention consisted of only three face-to-face consultations during a comparatively shorter time period (16 weeks), where patients were encouraged to reduce their sedentary behaviour in their everyday lives, still demonstrating significant health outcomes. This implies that even less resource demanding physical activity interventions may provide health benefits at an acceptable cost in patients with RA.

Although the JR-SB trial appeared to have sufficient statistical power to indicate differences in daily sitting time, physical function and HRQoL, the present cost-effectiveness analysis could not identify a statistically significant mean group difference in healthcare cost. The IG had lower mean cost for hospital inpatient services, GP and dentist services and higher cost for hospital outpatient services, services provided by general practitioners, primary care physiotherapists and medical specialists. However, none of these differences were statistically significant. The mean 22-month total healthcare cost for the IG was €1165 lower than for the CG, although the cost difference was not statistically significant. One possible explanation may be a large variation in healthcare resource use among patients with RA. Some patients will have relatively modest costs, while other patients will have extensive and costly use of healthcare resources. Recently, we conducted a retrospective, register-based trial[37] investigating sociodemographic and clinical characteristics of participants in the JR-SB trial compared with those patients initially declining to participate and to the general population of Danish patients with RA. The study showed that in comparison with decliners and the background population, participants in the JR-SB trial were younger, had longer education, performed more regular exercise and had fewer comorbidities.[37] Therefore, the sample of participants in the JR-SB trial may be a subsample with less use of healthcare resources than the general population of patients with RA. This should be considered when interpreting the results from the present study.

Strengths and weaknesses

One of the primary strengths of this cost-effectiveness analysis includes the origin of the data from a carefully designed clinical randomised trial with long-term follow-up and objective measures of behavioural changes. As such, the analysis included both objectively measured sitting time, self-reported physical function as well as self-reported scores on a standard economic outcome measurement (EQ-5D). The data collection was nearly complete with very few participants with incomplete outcome data. Also, data related to intervention cost was continuously registered during the development and course of the intervention, which made this cost-effectiveness analysis reasonable robust. Another strength involves the linkage of Danish health registries using the unique personal identification number, which made it possible to obtain healthcare data for each participant.

A methodological weakness of the analysis was the relatively small study population, which may imply that the study was not powered to identify a mean group difference in healthcare costs and that generalisation of the results should be done cautiously. Also, the reported NPV is likely to be under-reported as the positive health outcomes are likely to continue beyond the end of the trial period. In our report, we did not extrapolate the

findings into a longer time perspective as the empirical basis for doing so is missing, but also because it is unlikely to change the cost-effectiveness of the intervention. Finally, the analysis has been conducted with a healthcare perspective, which implies that resources outside the healthcare sector were not included. Inclusion of social service cost data may provide a broader understanding of the societal and economic value of the physical activity intervention offered to patients with RA.

This protocolised cost-effectiveness analysis showed that the JR-SB intervention reduces sedentary behaviour in patients with RA and improves participants' 22-month health status and reduce healthcare costs. These results propose that the intervention should be implemented in routine rheumatology care.

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Contributors Study conception and design: JS, BAE and TT. Acquisition of data: TT, BAE and JS. Data management and statistical analysis: JS. Analysis and interpretation of data: JS, BAE and TT. All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be submitted for publication. TT had full access to data obtained as part of the study and takes responsibility for the integrity of the data. JS takes responsibility for the overall content as the guarantor.

Funding The study as supported by grants from the Danish Rheumatism Association and the Lundbeck Foundation, the Tryg Foundation.

Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants. All study participants provided written informed consent to participate. The study was reported to the Danish Data Protection Agency (ref.nb. 711-1-08) and was approved by the Danish Health Research Ethics Committee System (ref.nb. H-2-2012-112) and was performed in compliance with the Declaration of Helsinki. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data may be obtained from a third party and are not publicly available. Data from the national health registries have been made available for analysis by Sundhedsdatastyrelsen, the Danish Health Board and have been analysed on their server.

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