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Room for improvement

– A randomised controlled trial with nested qualitative interviews on space, place and treatment delivery.

Author information

Louise F. Sandal[1], PhD, lsandal@health.sdu.dk

Jonas B. Thorlund[1], PhD, jthorlund@health.sdu.dk

Andrew J. Moore[3], PhD, a.j.moore@bristol.ac.uk

Roger S. Ulrich[2], Professor, PhD, roger.s.ulrich@gmail.com

Paul A. Dieppe[4], Professor, MD, p.dieppe@exeter.ac.uk

Ewa M. Roos[1], Professor, PhD, eroos@health.sdu.dk

[1]Department of Sports Science and Clinical Biomechanics, University of Southern Denmark, Odense, Denmark

[2]Department of Architecture, Chalmers University of Technology, Gothenburg, Sweden

[3]School of Clinical Science, University of Bristol, Bristol, United Kingdom

[4]Medical School, University of Exeter, Exeter, United Kingdom

Corresponding author:

Louise Fleng Sandal, Ph.D.

Department of Sports Science and Clinical Biomechanics, University of Southern Denmark, Campusvej 55, 5230 Odense M, Denmark

Phone: + 45 65 50 43 84, Email: lsandal@health.sdu.dk

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Abstract

Background/aim: Single elements within the physical environment promote better health-outcomes in hospitals. Creating optimal facilities for exercise therapy may increase treatment effects. We investigated the influence of the treatment room on effects of exercise therapy.

Methods: In a mixed-method randomised controlled double-blind trial, middle-aged individuals reporting knee or hip pain performed eight weeks of exercise therapy in A) a newly built physically enhanced environment, B) a standard environment or C) were waitlisted, receiving no intervention. Participants and therapists were blind to study aim. Primary outcome was participants' Global Perceived Effect (GPE, 7-point Likert scale). Six nested focus group interviews with participants (n=25) and individual interviews with therapists (n=2), explored experiences of the environment. Registration identifier: NCT02043613.

Results: 42 exercised in the physically enhanced environment, 40 in the standard environment, 21 were waitlisted. Participants from the standard environment reported greater improvement for GPE (0.98, 95%CI 0.5 to 1.4) than participants from the physically enhanced environment (0.37, 95%CI -0.2 to 0.9), between-group difference 0.61 95%CI -0.1 to 1.3, p=0.07, this was contrary to our hypothesis. In interviews, participants from the standard environment expressed greater social-cohesion and feeling at-home. Qualitative themes identified; reflection, sense of fellowship and transition. Waitlist group reported no improvement (-0.05 95%CI -0.5 to 0.4). Secondary patient-reported outcomes and qualitative findings supported the primary finding, while improvements in muscle strength and aerobic capacity did not differ between exercise groups.

Conclusion: Results suggest that the physical environment contributes to treatment response. Matching patients' preferences to treatment rooms may improve patient-reported outcomes.

Keywords: joint pain, treatment delivery, context effect, physical environment

INTRODUCTION

Healthcare oriented design in hospitals can promote better clinical outcomes[1, 2], and the relationship between the physical environment and patients' sense of well-being is well-documented.[3-5] From hospital environments single factors such as views of nature, light intensity, music, noise levels, etc. are reported to affect health outcomes, both positively and negatively.[1, 6-11]

In the United States, it is estimated that more than $200 billion will be spent on construction of new healthcare facilities between 2014 and 2017 to address the growing demand for healthcare in the aging population.[12] Consequently, construction and renovation of healthcare facilities presents as an opportunity to implement evidence-based design to improve health outcomes and reduce treatment costs.[2, 12] Although evidence-based and participatory design processes increasingly are informing hospital construction and design[13], little evidence exists on how the physical environment may influence health outcomes in settings other than hospitals, such as rehabilitation and exercise facilities.

The physical environment constitutes a potential mechanism of the placebo effect.[9, 14, 15] In medical research the treatment effect is typically quantified as the difference between treatment and placebo groups, which disregards the contribution of placebo mechanisms to the within-group treatment response.[15-17] From a clinical perspective it is the overall treatment response that is important. Consequently all aspects of being treated should be considered, [15] including contributions from the physical environment. Research aiming at disentangling the attribution from placebo or contextual factors from a "real" treatment response may not only help explain variation between findings in clinical trials, but may also help enhance overall treatment effects in clinical

practice. The aim of this study was to investigate the influence of the physical environment on exercise therapy, a recommended treatment for knee and hip pain.[18-20]

METHODS

Study design

The study was a 3-armed double-blind randomised controlled clinical trial (RCT) with nested qualitative interviews. The detailed study protocol has been published.[21] The study was approved by The Regional Scientific Ethical Committee for Southern Denmark (S-20130130), registered at ClinicalTrials.gov (NCT02043613) and complies with the Helsinki Declaration. After giving written informed consent, participants were consecutively randomised by a computer-generated list in a 2:2:1 allocation to either A) exercise in a physically enhanced environment, B) exercise in a standard environment or C) a waitlist. The trial was double blind, as both participants and therapists were blind to the primary study aim, to investigate the influence of the physical environment on treatment outcome. Blinding of participants to the study aim was approved by the Ethics Committee. Participation was motivated by wanting to start exercise as treatment. The outcome assessor and the third party performing data analysis were blinded to treatment allocation.

Participants

Recruitment was conducted through posters and leaflets at general practitioner clinics or participant-initiated contact via local newspapers and social media. Eligible participants were 35 years or older with self-reported persistent knee or hip pain within the last 3 months (yes/no question), willing and able to attend group-based exercise therapy twice weekly at the University of Southern Denmark, Odense. Exclusion criteria were: Co-morbidities or contraindication prohibiting exercise therapy; inability to speak, read or understand Danish; already participating in exercise

therapy aimed specifically at relieving joint pain, or surgery to the hip/knee within three months or awaiting surgery.

Intervention

Physical environments

The only difference between the intervention groups A and B was in location, age and appearance of the exercise rooms. The physically enhanced environment (group A) appeared new and modern, whereas the standard environment (group B) appeared old and worn. See Table 1 for room characteristics and the supplementary material for additional pictures. The physically enhanced environment entailed several characteristics (view of nature, sunlight, decorations, good acoustics) previously reported to affect health positively in hospital settings.[1, 6, 10] Consequently, group A was a-priori hypothesized to report greater improvement compared to group B.

Table 1: Characteristics of exercise environments	**Physically enhanced environment**	**Standard environment**
Description	The exercise environment is located in a newly built facility on the second floor and has a vista over a sport and recreational park. The room is a designated exercise room. It appears clean and new, with rubberized floors, smooth concrete walls. Decoration includes pictures of landscapes. It is equipped with state of the art exercise equipment.	The exercise environment is marked by years of use and resembles many existing exercise facilities at hospitals and rehabilitation clinics. It is located in the basement of an older campus building and has no windows. Access through a series of staircases and dark hall-ways. The room appears used with polished wooden floors, wall-bars, bare, unadorned concrete walls.
Year building completed	2012	1974
Picture	 	 
Participant satisfaction		
(range 0-5)		
Physical environment (p=0.00)	3.9 (95% CI 3.6 to 4.1)	3.4 (95% CI 3.2 to 3.6)
Exercise intervention (p=0.45)	4.3 (95% CI 4.1 to 4.5)	4.4 (95% CI 4.2 to 4.7)
Interior		
Wall decorations (y/n)	y	n
Vista/windows (y/n)	y	n
Music during exercise (y/n)	y	y
Light		

Source	Daylight + artificial	Artificial
Strength (Lux)	2168 (SD: 744)	552 (SD: 39)
Air quality		
CO_2 (ppm)	Supplementary material	Supplementary material
Temperature (°C)	Supplementary material	Supplementary material
Humidity (%)	Supplementary material	Supplementary material
Sound/noise (SD)		
Background noise (dB(A))	31.8 (SD: 3.9)	41.2 (SD: 2.4)
Speech Clarity Index (C50),	1.8 (SD: 1.3)	0.7 (SD: 0.8)
Speech Transmission Index (STI)	0.7 (SD: 0.0)	0.6 (SD: 0.0)
Reverberation (T20)	0.92	0.95
Interpretation from acoustician	Generally, all four acoustic measurements favour the physically enhanced room environment over the standard environment, the differences were however small. Regarding reverberation, the standard environment has higher numbers in the low frequency area, which are perceived as echoing in the room.	

Table 1: Satisfaction scores range from 0-5, worst to best. Satisfaction with the physical environment is a total score compiled from 11 single items (general satisfaction, lighting, access road, colour in room, décor, noise level, air quality, temperature, cleanliness of exercise room and changing room, location of room). Satisfaction with exercise intervention is a total score compiled from 2 single items (satisfaction with exercise in general and satisfaction with communication with therapist). Mean with 95% confidence intervals are presented. Ppm: parts per million, C50, clarity index with first 50 msec of sound (mean across frequencies from 250Hz to 8kHz, higher is better); STI: speech interpretability index, T20: reverberation time for sound decay of 20 dB (from 400Hz-1,25kHz). SD; Standard Deviation. All acoustic measurements are available on request to the author.

Exercise therapy programme

The physiotherapist-supervised group-based NEuroMuscular EXercise (NEMEX) programme was delivered in both exercise groups for one hour, twice weekly for eight weeks. The programme is progressed, but individualised to each participant's starting level.[22] NEMEX is effective in relieving pain and improving function in populations with knee or hip pain.[22-24] To ensure consistency in therapist-participant interaction the therapists supervised both exercise groups. In total, six therapists supervised the exercise therapy during the trial.

Waitlist

Participants randomised to the waitlist (group C) were on a passive waitlist for eight weeks, and then offered eight weeks of gym-based exercise after completing their follow-up assessment. This group acted as an untreated control group.

Outcome measures

Clinical examinations and demographic characteristics were obtained at baseline. Patient-reported outcomes were collected electronically in the clinic at baseline and 8-weeks and from home at 4-weeks. Physical performance tests were assessed at baseline and 8-week follow-up after completion of the electronic survey.

Primary outcome

A 7-point Global Perceived Effect (GPE) score was administered at 8-weeks follow-up.[25] Participants responded to the following question; *"Compared to when entering the study, how are your knee/hip problems now?"* The GPE scale ranged from '[-3] = markedly worse' through '[0] = no change' to '[3] = markedly improved'.

Secondary outcomes

Change from baseline to 8-week follow-up was assessed for all secondary outcomes; Knee injury and Osteoarthritis Outcome Score (KOOS)/Hip disability and Osteoarthritis Outcome Score (HOOS) depending on pain location;[26, 27] the Short Form Health Survey (SF-36);[28] a modified version of Arthritis Self-Efficacy Scale (ASES);[29] participants' stress level; satisfaction with the exercise intervention; satisfaction with the physical environment;[30] single limb mini-squat;[31] number of knee bends on one leg during 30 sec;[32] number of chair stands during 30 sec;[33] 40m fast-paced walking time,[33] one leg hop for distance;[32] aerobic capacity (Åstrand's bike ergometer test) and maximal isometric muscle strength (knee extension, hip abduction). Compliance with exercise therapy was considered good if participants attended 12 of 16 exercise sessions. Adverse events were self-reported at four and eight weeks in the electronic survey or recorded by the supervising therapist if occurring during exercise sessions.

Nested qualitative interviews

Three focus group interviews were conducted by LFS on a convenience sample of 13 participants from the physically enhanced environment and three focus group interviews with 12 participants from the standard environment.[34] Participants were informed that the aim of the interviews was to evaluate all aspects of their participation in order to optimize treatment delivery. The interview topic-guide (supplementary material) initially focused on participants' general experiences, followed by narrower questions on perceptions of the physical environment. A photo-elicitation technique, showing photographs of the exercise environment helped focus participants' dialogue on the physical environment .[35-37] Face-to-face individual interviews (conducted by LFS) with two supervising therapists explore therapists' experiences and perceptions of the exercise rooms. Focus-group interviews lasted between 71-104 minutes; face-to-face interviews lasted 64 and 76 minutes. All interviews were conducted between two and 12 weeks after completion of participants' 8-week

follow-up assessment. Interviews were audio-recorded with participants' written consent, transcribed verbatim and anonymized. Both individual and focus group interviews were deductively and inductively coded using QSR Nvivo11 data management software and analysed using the Framework approach.[38] Themes were identified and compared within and across the two exercise environments in both focus groups and individual interviews. Qualitative data were analysed prior to the quantitative data and interpretation of the qualitative findings was therefore unbiased by the quantitative results.

Statistical analysis

Details of the sample size calculation, randomisation process and analysis procedure have been described.[21] The study was powered to detect a 0.75 difference in GPE (SD 1.2, significance level of 0.05, 80% power, 40 participants/group). The statistical analysis plan was made publicly available at the University website prior to conducting data analysis.[39] The primary outcome analysis was performed by a blinded independent third party.[21] To reduce the risk of bias the authors agreed in writing on two alternative interpretation scenarios prior to breaking the randomisation code.[40]

A Student's unpaired t-test based on the ITT principle was used to test the primary endpoint.[39] A linear test for trend was performed across all groups to explore the a-priori hypothesis of a graded relationship between groups: waitlist < standard environment < physically enhanced environment. A per-protocol analysis was performed including participants attending 12 of 16 possible exercise sessions or more. Secondary analyses were performed as repeated measures using a multilevel mixed-effect model with participants as random effects, time, group and interaction between time and group as fixed effects. All available data points were included.

RESULTS

Enrolment

In the period from January 29th to November 18th 2014, 103 participants were randomised: 42 to the physically enhanced environment, 40 to the standard environment and 21 to the waitlist group (Fig.1). One participant in the physically enhanced environment and one in the waitlist group were lost at 8-weeks follow-up for the primary outcome.

Participant characteristics

Groups were comparable at baseline (Table 2 & supplementary material table 1). The mean age of the study population was 58.5 years (SD 9.9 years), 61% were women, 63% had knee pain, 88% reported pain for more than one year and 59% had clinically diagnosed osteoarthritis according to the American College of Rheumatology criteria.[41]

Table 2: Baseline characteristics for participants	**Physically enhanced environment** n=42	**Standard environment** n=40	**Waitlist** n=21	p-value
Women, n, (%)	25 (60%)	25 (63%)	13 (62%)	0.96
Age (years), mean (SD)	59.6 (10.9)	57.6 (9.8)	58.2 (7.9)	0.65
BMI, mean (SD)	28.4 (5.0)	28.0 (5.8)	29.1 (7.0)	0.79
Medical comorbidities, participant median pr. group, n,	2	1	2	0.276
Index joint, knee (%)	26 (62%)	26 (65%)	13 (62%)	0.95
Clinical OA diagnosis, n, (%)	22 (52%)	26 (65%)	13 (62%)	0.48
Pain index joint, NRS, mean (SD)	3.9 (2.0)	3.6 (2.2)	4.1 (2.4)	0.57
Pain duration, n, (%)				0.61
0-6 months	1 (2%)	3 (7.5%)	0 (0%)	
6-12 months	4 (10%)	3 (7.5%)	1 (5%)	
1-5 years	20 (48%)	14 (35%)	11 (52%)	
< 5 years	17 (40%)	20 (50%)	9 (43%)	
Physical activity level, n, (%)				
Work				0.35
Very light	12 (29%)	9 (23%)	10 (48%)	
Light	11 (26%)	8 (20%)	5 (24%)	
Moderate	11 (26%)	18 (45%)	4 (19%)	
Strenuous	2 (5%)	2 (5%)	0 (0%)	
Unemployed	6 (14%)	3 (7%)	2 (9%)	
Leisure				0.12
Very light	4 (9%)	1 (3%)	0 (0%)	
Light	5 (12%)	9 (22%)	6 (29%)	
Moderate	18 (43%)	16 (40%)	5 (24%)	
Active	10 (24%)	14 (35%)	8 (38%)	
Very Active	5 (12%)	0 (0%)	2 (9%)	

Table 2: SD, Standard Deviation, BMI, Body Mass Index, OA, osteoarthritis, NRS, Numerical Rating scale ranging from 0 - 10. Medical comorbidities are given as participants median for the group, comorbidities include heart disease, elevated blood pressure, lung disease, diabetes, ulcer, kidney or liver disease, anaemia, cancer, depression, arthritis, lower back problems, rheumatic disease or other self-reported medical comorbidities

Primary outcome

The waitlist group reported no significant improvement (-0.05 GPE CI 95% -0.5 to 0.4), and both exercise groups combined significantly improved compared to the waitlist group, p=0.05. However, contrary to our hypothesis, the treatment response seemed to be greater in the standard environment (0.98 GPE, CI 95% 0.5 to 1.4) compared to the physically enhanced environment (0.37 GPE, CI 95% -0.2 to 0.9), though this difference of 0.61 GPE (CI 95% -0.1 to 1.3) did not reach statistical significance (p=0.07) (Fig. 2). Due to the unexpected reversed order of treatment response the pre-specified test for trend across groups was no longer relevant. The per protocol analysis, including participants attending at least 12 of 16 exercise sessions, similarly favoured the standard environment (standard environment 1.3 GPE, CI 95% 0.9 to 1.7, physically enhanced environment 0.8 GPE CI 95% 0.3 to 1.4, p=0.20), and suggests a positive relation between dose of exercise and treatment response.

Secondary outcomes

The primary and all secondary outcomes data are summarized in Fig. 2. All patient-reported secondary outcomes supported the direction of the primary finding favouring the standard environment. Improvement in the knee bending performance test was larger for participants from the standard environment. However, no differences between groups were observed for aerobic capacity or muscle strength. Within-group changes and between-group differences are given in supplementary material table 1. A transient exercise-induced pain flare was the most commonly reported adverse event (appendix table 2 and [42]).

Qualitative findings

The qualitative interviews provided insight into participants' direct and symbolic reflections upon the exercise environments ("reflections"), how participants' impressions of the space changed over time ("transitions"), and the sense of social-cohesion that participants felt ("sense of fellowship"). Illustrative quotes in table 3.

Reflections

Participants exercising in the standard environment described a symbolic reflection as they felt the old, worn room reflected their own physical state, they did not perceive the aged appearance negatively. Furthermore, participants expressed a pronounced feeling of being 'at-home' in the standard environment and expressed nostalgia towards the room as it reminded them of their school gyms *(quote 3).*In both environments, mirrors directly reflected participants' bodies, providing visual feedback and helping them to improve movements during exercises. However, participants avoided the mirrors, feeling uncomfortable about their reflection while exercising (quote 1-2). Participants, from both environments, associated mirrors with commercial gym facilities, which they perceived as an inappropriate place for exercise therapy.

Sense of fellowship

An important difference was the sense of fellowship felt within each environment. All participants, regardless of room allocation, expressed a sense of social-cohesion as everyone had joint pain and felt obligated towards the project, therapists noticed this participant obligation as well. For logistic reasons participants were continuously enrolled in the exercise groups. This was perceived as interruptive, indicating that participants liked continuity in the group dynamics. In both environments, music during exercise provided a subject of conversation and therapists described it as ´protective´ as it broke the silence. Large windows in the physically enhanced environment

provided positive distraction from the monotony of exercise and gave participants a feeling of being part of a larger community. Although the music and view in the physically enhanced environment were described positively, they seemed to distract participants from interacting socially with each other. Participants exercising in the physically enhanced environment explicitly stated that they did not feel a social connection with each other, whereas participants from the standard environment described a strong sense of fellowship (quotes 4-5). Without the distraction from the outside view combined with the austerity of the space, participants in the standard environment seemed more conscious of each other, felt safer to interact and at-home in the environment.

Transition

Participants described markedly different experiences in their journey into the two environments. Participants exercising in the physically enhanced environment described their journey positively (quote 6-7). They ascended an open stairway and as this room was located in a multi-purpose Sports facility, they felt included in a larger exercise community. Contrarily, participants exercising in the standard environment descended an enclosed stairway leading to a dark basement that was described as "unwelcoming". Several participants felt "unsafe" when attending the first session (quote 8). These transitions were pivotal for participants' first impression of the environments. For participants exercising in the standard environment their initial negative impression changed over time, as they imbued the space with more positive meaning based on their experiences, consequently transforming the space into a therapeutic place.

Table 3: participant quotes	"Reflections"	"Sense of fellowship"	"Transition"
Physically enhanced environment	(1) *"LS (moderator)* *Did you use the mirrors as well, Maja and Ida?* *Maja:* *Yes, well eh. As I remember it, we were asked to come wearing shorts, well at least for the testing. I wore those shorts for the first exercise session as well. That was scary, it did not happen again. It was leggings from then.* *LS (moderator)* *Yes, why was it scary?* *Maja:* *Well it was just, looking at those untrained legs {laughs}"* *(Maja, focus group 5)*	(4) *Mette:* *I think it would have been better on a team. […] Then you could hold each other to it; "Now remember to attend next time". It's easier to stay away when no one is holding you to it. […]* *LS (moderator):* *You didn't have a feeling of being part of a team while you were here?* *Jens:* *No, I didn't.* *Anne:* *No, I didn't think so."* *(Focus group 5)*	(6) *"I think it was great as you say. To go into the changing room down in the basement and up the stairs and... Really, the whole process with starting. I thought it was good. It would not be the same in a gym or a physical therapist, really. I like it here. There is a little character of a club or something."* *(Peter, focus group 4)* (7) The group is talking about what they first noticed about the exercise environment and they are talking about the stairs leading up to the exercise environment. *"LS (moderator)* *Yes, why did you think of those, Lene?* *Lene:* *Well, it's people with bad knees and bad hips, then it is hard getting up and down, right?.* *LS (moderator):* *Right? So did you see them as a hindrance or an obstacle?* *Lene:* *Eh, no. I didn't. I saw them as a challenge. {laughs}. Yes, and I would also say that then after a couple of weeks of coming here, then it was easier getting up the stairs."* *(focus group 6)*
Standard environment	(2) "*I have a phobia of mirrors."* *(Hanne, focus group 3)* (3) *"I also know that it means something that you feel at-home in the place you are in and I think that I did"* *(Mia, focus group 1)*	(5) *"From my perspective it is something that motivates […] that there's a good atmosphere. And it is only there, when we feel comfortable and safe. […] It has a contagious effect. […] That social, I don't know, sense of community perhaps. We were there for the same reason and we all had something to fight with, more or*	(8) *"Sisse:* *Yes, we would walk down that spooky hall-way* *LS:* *Yes? Did you feel unsafe there?* *Thomas:* *I didn't* *Tove:*

	less." *(Tina, focus group 3).*	*Yes…!!* *Sisse:* *Not particularly* *Hans:* *I didn't* *Thomas:* *I didn't either* *Tove:* *Yes, I did. Less if there wasn't anybody there, but when a student was walking with their bikes or something, yes, then I felt unsafe.* *Louise:* *In the hall-way?* *Tove:* *Yes, and when I was walking to my bike. Well, where I would park my bike, when we would go home. Then it was…* *Sisse:* *…very dark.* *Tove:* *Very dark.* *It was very reclusive* *Sisse:* *Yes."* *(focus group 2)*

Table 3: Illustrative quotes from focus group interviews performed with participants from both environments. All interviews have been transcribed verbatim and all participants are anonymised with pseudonyms. [] indicates that part of the conversation has been taken out, as it was not relevant for the analysis and understanding of the conversations. {} indicates any non-verbal responses or actions.

DISCUSSION

We compared exercise therapy performed in a physically enhanced environment with exercise therapy performed in a standard, older environment. Contrary to the a priori hypothesis, the treatment response seemed to be greater in the standard environment compared to the physically enhanced environment, though it did not reach statistical significance for the primary outcome (p=0.07). Patient-reported secondary outcomes and per protocol analyses supported the direction of the primary outcome. The qualitative interviews similarly supported the primary finding and provided possible explanations, as participants exercising in the standard environment reported feeling more at-home and safe, and experienced a sense of fellowship to a greater extent than those in the physically enhanced environment.

In this novel randomised trial, we investigated the influence of the physical environment on treatment effects in an exercise setting. Previous studies performed in hospital environments have reported on single factors within the physical environment, where for example light intensity, exposure to daylight and view to nature scenes enhanced treatment effects in postoperative patients.[6, 10] These single factors did not produce a similar response in our exercise therapy setting. Another unique characteristic of our trial was the group-based intervention and the repeated one-hour visits during 8 weeks to the health-care facility, whereas previous studies have investigated single admissions of consecutive days for individually treated patients. The discrepancies between our results and previous studies suggest that the influence of the physical environment may depend on factors such as patient groups, treatment duration, types of interventions and health-care settings.

Placebo or context effect as a multifactorial concept

Previous studies investigating placebo or the influence of context mechanisms on treatment response have mostly focused on the patient-practitioner relationship. Suarez-Almazor et al. reported greater pain relief in knee osteoarthritis patients treated by a practitioner expressing high compared with neutral expectations of treatment effects.[43] The patient-practitioner relationship is considered the most important component of the placebo, or context effect.[14, 44] However, several other factors may act as mediators, including characteristics of the practitioner, patient or treatment, severity of disease, and the physical environment where treatment is delivered.[14, 17, 45] The current study and two previous studies[43, 46] attempt to isolate one specific factor's contribution to the treatment effect by applying a randomised study design. However, the addition of qualitative interviews in our trial suggested that the physical environment can influence the social and psychological context that participants experience while exercising. Consequently, a mediating effect of the physical environment on social cohesion may be a potential mechanism of enhanced treatment effect. This is similar to previous studies reporting that group-based therapy was perceived as more attractive than individual care by some older patients receiving physiotherapy.[47, 48] These results suggest that rather than isolating one particular aspect of the context effect, interactions of all potentially mediating factors intertwined should be considered. Such mediating effect may be utilised clinically to enhance treatment effect by optimization of overall treatment delivery.

We observed greater differences in the patient-reported outcomes than the functional performance tests, and no differences were seen in aerobic capacity or muscle strength (Fig. 2). This is in line with previous studies and a systematic review finding greater placebo or contextual effect in patient-reported outcomes and in diseases defined by patient-reported symptoms.[45, 46] We suggest future trials to include both patient-reported and objectively assessed outcomes to better elucidate mechanisms involved in treatment response.

Methodological considerations

We used a 3-armed RCT design to separate components of the observed treatment effect.[17, 45] Adding a passive waitlist group to the study design excluded the possibility that the observed treatment effect was caused by natural disease remission.[49] As therapists supervised in both environments, the interaction between participants and therapists was consistent between groups. The effect size in the primary outcome was 0.49 when comparing the combined exercise groups to the waitlist group. An effect size of 0.5 is considered moderate, and corresponds to the effect of exercise therapy for knee osteoarthritis pain.[50] Although we observed dissimilar percentages of participants discontinuing exercise from the two environments, 21% vs. 5% (figure 1), attrition bias seems unlikely as all but one participant completed the primary outcome for the primary analysis. Multiple testing of many outcomes increases the risk of chance findings. However, the directionality in primary and secondary outcomes was the same and was supported by the qualitative findings.

In conclusion, this study investigated the influence of the physical environment on exercise therapy in a randomised controlled design. The study results suggest that the physical environment may affect treatment outcome. Giving greater attention to matching the physical environment to the preferences of the intended users may improve patient-reported treatment effects from interventions such as exercise therapy.

List of abbreviations

RCT: Randomized Controlled Trial.

GPE: Global Perceived Effect

NEMEX: Neuromuscular exercise.

KOOS: the Knee Osteoarthritis and injury Outcome Score

HOOS: the Hip disability and Osteoarthritis Outcome Score

SF-36: Short-Form (36 item) Health Survey

ASES: Arthritis Self-Efficacy Scale

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Competing interests

The authors declare no competing interests.

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Author contributions

LFS, JBT, RU, PD and ER were all involved in the design of the study. All authors contributed to drafting the manuscript or revising it. LFS, JBT and ER comprise the steering committee for the

study. LFS was the trial manager and responsible for the coordinating and conducting the study. LFS recruited, screened and conducted all baseline and follow-up testing and is responsible for the accuracy of the data and data-analysis. LFS, PD and AM designed nested qualitative study, LFS performed all interviews, AM supervised the qualitative data collection process, AM and PD contributed to the analysis of the qualitative data. All authors read, commented and approved the manuscript for publication.

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