■ CHILDREN'S ORTHOPAEDICS

Virtual reality reduces anxiety of children in the plaster room: a randomized controlled trial

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Aims

Paediatric fractures are highly prevalent and are most often treated with plaster. The application and removal of plaster is often an anxiety-inducing experience for children. Decreasing the anxiety level may improve the patients' satisfaction and the quality of healthcare. Virtual reality (VR) has proven to effectively distract children and reduce their anxiety in other clinical settings, and it seems to have a similar effect during plaster treatment. This study aims to further investigate the effect of VR on the anxiety level of children with fractures who undergo plaster removal or replacement in the plaster room.

Methods

A randomized controlled trial was conducted. A total of 255 patients were included, aged five to 17 years, who needed plaster treatment for a fracture of the upper or lower limb. Randomization was stratified for age (five to 11 and 12 to 17 years). The intervention group was distracted with VR goggles and headphones during the plaster treatment, whereas the control group received standard care. As the primary outcome, the post-procedural level of anxiety was measured with the Child Fear Scale (CFS). Secondary outcomes included the children's anxiety reduction (difference between CFS after and CFS before plaster procedure), numerical rating scale (NRS) pain, NRS satisfaction of the children and accompanying parents/guardians, and the children's heart rates during the procedure. An independent-samples *t*-test and Mann-Whitney U test (depending on the data distribution) were used to analyze the data.

Results

The post-procedural CFS was significantly lower ($p < 0.001$) in the intervention group (proportion of children with no anxiety = 78.6%) than in the control group (56.8%). The anxiety reduction, NRS pain and satisfaction scores, and heart rates showed no significant differences between the control group and the intervention group. Subanalyses showed an increased effect of VR on anxiety levels in young patients, females, upper limb fractures, and those who had had previous plaster treatment.

Conclusion

VR effectively reduces the anxiety levels of children in the plaster room, especially in young girls. No statistically significant effects were seen regarding pain, heart rate, or satisfaction scores.

Cite this article: *Bone Joint J* 2024;106-B(7):728–734.

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doi:10.1302/0301-620X.106B7.BJJ-2023-0756.R2 $2.00

Bone Joint J 2024;106-B(7):728–734.

Introduction

Fractures occur frequently in children: in the Netherlands, the prevalence of paediatric fractures varies between 28% and 40%.[1] Most paediatric fractures are treated with a plaster cast. The application and/or removal of plaster is often an anxiety-inducing experience for children, particularly under the age of 13 years.[2,3] To improve their hospital experience and quality of healthcare for these children, a method to effectively reduce this anxiety is desirable.

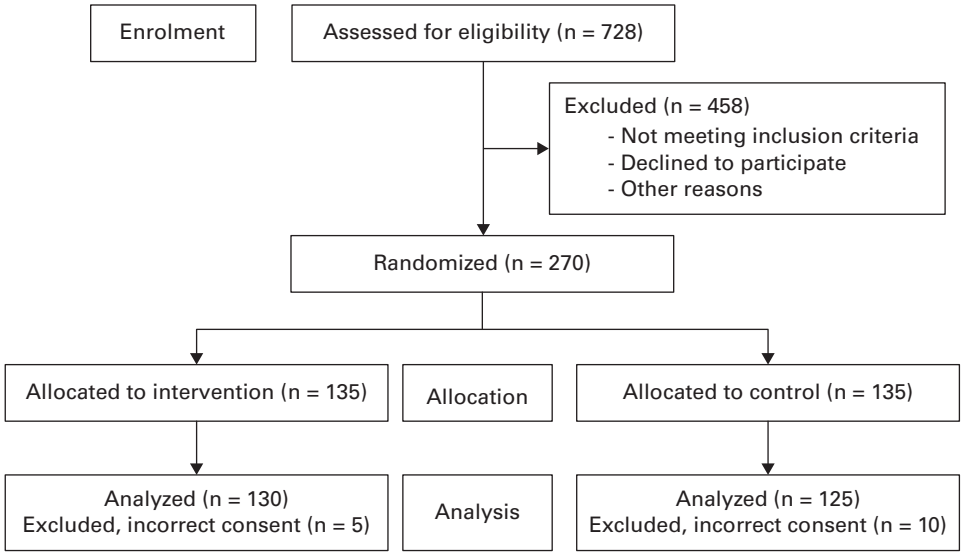

Fig. 1

Consolidated Standards of Reporting Trials (CONSORT) flow diagram showing inclusion, randomization, and participation.

Different methods to reduce anxiety have been investigated in children in various clinical situations.[4,5] Both visual distraction and noise reduction could have a positive effect on the anxiety levels of children.[6] Although some investigated methods have proven to be ineffective, including using medication such as Midazolam and showing an instructional video ahead of the procedure,[4,5] a few methods have been shown to improve anxiety levels, such as watching videos on a smartphone or tablet during the procedure, and using noise-reducing headphones during plaster removal.[2,7,8] These findings might indicate a role for virtual reality (VR) as an effective distraction method.

VR has been used in some clinical settings to visually distract patients from anxious situations. VR has demonstrated a reduction in anxiety and pain perception in children in several clinical situations, such as blood withdrawal, dental procedures, intravenous injections, and treatment of burns.[9-12] During phlebotomy, the use of VR has been shown to be more effective in reducing anxiety and pain perception than watching a video on a tablet.[8]

Jivraj et al[13] recently published the first effects of VR during plaster removal in a small group of diverse paediatric orthopaedic patients, and found that it significantly reduced their anxiety levels. The aim of the present study was to further investigate the anxiety-reducing effects of VR goggles and headphones in a large group of children with fractures who needed plaster replacement or removal.

Methods

This study was a single-centre randomized controlled study. The study was approved by the MEC-U (NL75353.100.20), a recognized medical research ethics committee. The trial was registered in the International Clinical Trials Registry Platform (ICTRP) (NL9065) on 27 November 2020.[14] The design and reporting of this trial followed the Consolidated Standards of Reporting Trials (CONSORT) statement.[15]

Children between the age of five and 17 years who underwent replacement or removal of plaster for a fracture in the upper or lower limb were included. The children were randomized between treatment with (intervention group) or without a VR goggle (control group). A computer-controlled randomization through Castor Electronic Data Capture system (EDC) (Netherlands) was used. The randomization was stratified for age (five to 11 and 12 to 17 years). Each patient only participated once in this study. Children with known learning difficulties, anxiety disorders, psychosis, epilepsy, and extreme visual impairment (i.e. myopia > 8 dioptres or presbyopia > 5 dioptres) were excluded from this study. All participating children and their parents/guardians provided written informed consent.[14] The patients were recruited between 21 January 2021 and 8 April 2022.

A total of 270 children were included in this study, of whom 255 were analyzed (control n = 125, intervention n = 130) because of 15 dropouts (Figure 1). These dropouts were not included in the analysis due to incorrectly filled-out consent forms. The patients' mean age was 10.7 years (SD 3.5) in the control group and 10.5 years (SD 3.2) in the intervention group. The patient and study demographic data are shown in Table I.

Control group. The control group received standard care consisting of the orthopaedic doctor or doctor in training explaining the procedure, and then removing and/or applying the plaster.

Intervention. The intervention group received standard care and wore VR goggles (Oculus Go or Oculus Quest 2; Facebook Technologies, USA) and headphones (JBL JR300 Junior; HARMAN International, USA) during the plaster treatment. After the orthopaedic doctor or doctor in training explained the plaster procedure, the investigator mounted the VR goggles and headphones on the child's head and started the video. After the plaster procedure, the VR goggles and headphones were removed. The total intervention took about two to four minutes longer in comparison with the control group.

Table I. Patient and study demographic data.

Characteristic	Control	Intervention	Total, n (%)	p-value*
Total, n	125	130	255	
Age group, n				0.794
5 to 11 yrs	77	78	155 (60.8)	
12 to 17 yrs	48	52	100 (39.2)	
Sex, n				0.295
Female	63	57	120 (47.1)	
Male	62	73	135 (52.9)	
Use of analgesics, n				0.635
No	119	122	241 (94.5)	
Yes	6	8	14 (5.5)	
Type of plaster treatment, n				0.897
Removal	97	100	197 (77.3)	
Replacement	28	30	58 (22.7)	
Method of plaster removal, n				0.187
Scissors only	84	77	161 (63.1)	
Saw and scissors	41	53	94 (36.9)	
Video choice, n				
Masha and the Bear	N/A	25	25 (19.2)	-
The Thundermans	N/A	53	53 (40.8)	-
Modern Family	N/A	28	28 (21.5)	-
Brooklyn Nine-Nine	N/A	24	24 (18.5)	-

*Mann-Whitney U test.
N/A, not applicable.

Each age group (five to 11 and 12 to 17 years) in the intervention group had a choice between two videos of approximately 20 minutes long. The videos were single episodes of different comedy series on a streaming service. Children between the ages of five and 11 years had a choice between *Masha and the Bear* (Season 1, Episode 2) and *The Thundermans* (Season 1, Episode 2); children aged 12 to 17 years could choose between *Modern Family* (Season 1, Episode 2) and *Brooklyn Nine-Nine* (Season 1, Episode 2). The videos were selected after a short pilot at the plaster room, where children were asked which videos they liked the most.

Outcome measures. The following demographic data were collected: date of plaster intervention, any previous plaster treatment, sex, age, type of plaster treatment (plaster replacement or removal), upper or lower limb fracture, specific location of fracture, and use of analgesics.

Before the procedure, the child's anxiety and pain scores were collected with a short questionnaire, using the Children's Fear Scale (CFS)[16] (Figure 2) and the numerical rating scale (NRS pain), respectively. The NRS ranges from 0 to 10, with 0 representing a complete absence of pain and 10 representing the highest level of pain. Both scales have been validated in the setting of hospitals for children.[16,17] The questionnaire regarding the CFS and NRS was administered directly after treatment.

During the plaster procedure, the child's heart rate was measured with a finger pulse oximeter (Onyx Vantage 9590; Nonin Medical, USA). After the treatment, anxiety and pain scores were collected again using the CFS and NRS Pain. Additionally, the child and accompanying parent/guardian were asked to provide their satisfaction with the procedure, using a NRS of satisfaction.

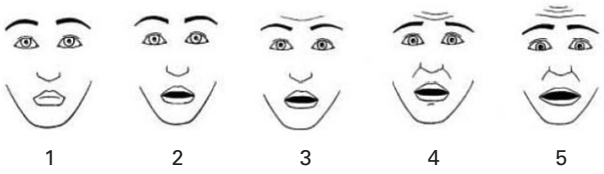

Fig. 2

Children's Fear Scale, ranging from 1 to 5, 0 indicating no fear and 5 indicating the most fear.

The primary study outcome parameter was the difference in post-procedural anxiety scores between the intervention and control groups, using the CFS. The secondary study parameters were the differences between the two groups in: anxiety reduction (difference between the child's CFS score pre- and post-procedural), NRS pain given by the child (pre- and post-procedure), NRS satisfaction given by the child and accompanying parent/guardian, and the child's maximum heart rate during the procedure.

Sample size calculation. Based on the literature, the mean expected anxiety score (CFS) in the control group was 1.78 (standard deviation (SD) 1.40).[16] For an intended improvement by 0.5 points (i.e. to 1.28) on the CFS, with a statistical power of 80% and α of 0.05, a sample size of 123 participants was needed in each group. An improvement of 0.5 points on the CFS was chosen because of clinical relevance and feasibility. To anticipate 10% dropout, we included 135 children in each group, 270 children in total.

Statistical analysis. Descriptive statistics were provided for the baseline demographic data. For the primary study parameter, the post-procedural CFS, the intervention and control groups were compared with use of the Mann-Whitney U test, because the data were not normally distributed. For the secondary study parameters of CFS reductions and NRS pain, the two groups were also compared using the Mann-Whitney U test. For NRS satisfaction and heart rates, an independent-samples *t*-test was used, given the normal distribution of the data. Subgroup analyses were performed, based on age (five to 11 and 12 to 17 years), sex (female and male), type of plaster treatment (plaster removal and plaster replacement), method of plaster removal (saw and scissors compared to scissors only), the fractured limb (upper and lower), and the use of analgesics. The statistical package SPSS (version 28; IBM, USA) was used for all statistical analyses. Statistical significance levels were adjusted to multiple testing according to the Holm method, for primary outcomes, secondary outcomes, and the subanalyses.[18]

Results

Most participants had a fracture of the upper limb (n = 236; 80.6%). The most common fractures were the distal radius (n = 138; 58.5%), distal ulna (n = 34; 14.4%), and the hand (n = 33; 14.0%) (Supplementary Table i). There were also a number of fractures classified as 'other': in total 18 fractures, including distal tibia, distal fibula, and isolated mid-shaft radius. In some patients, two fractures occurred simultaneously,

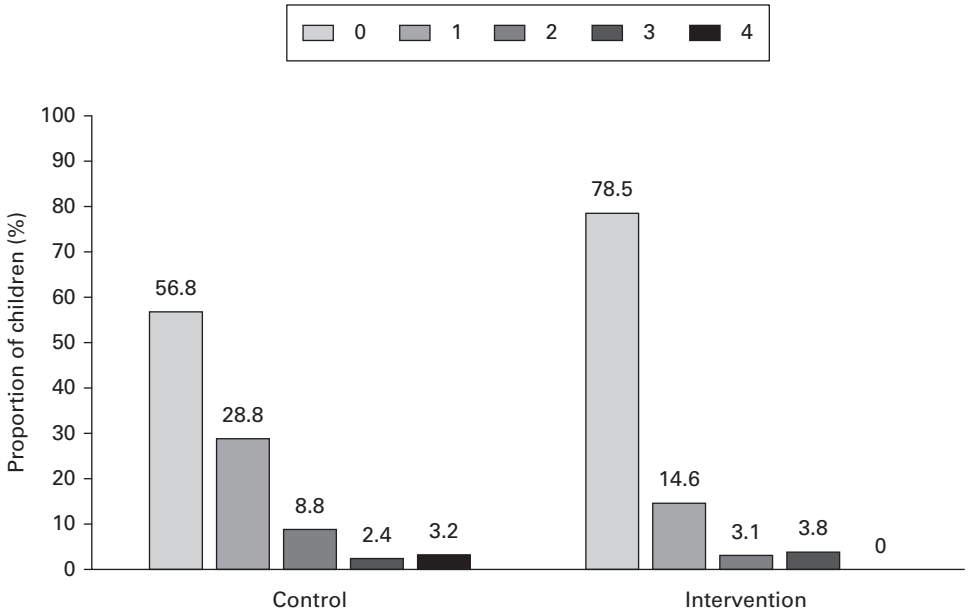

Fig. 3

Bar chart showing the post-procedure Children's Fear Scale.

the most common being distal radius with distal ulna and proximal radius with proximal ulna.

Outcomes. The post-procedural level of anxiety was significantly lower in the intervention group (proportion of children with CFS 0 = 78.6%) than in the control group (proportion 0 = 56.8%; $p < 0.001$) (Figure 3).

In contrast, anxiety reduction (pre-procedural CFS minus post-procedural CFS) was not significantly different between the intervention and the control groups (Table II). Other secondary outcome measures were not significantly different either (Table II). For example, the overall satisfaction scores were very high, with 225 (88.3%) patients scoring 8.0 or higher on the NRS, with no effect of VR. Overall, 45 (17.6%) patients experienced pain before and 72 (28.2%) after the procedure; 54 (21.2%) patients experienced an increase in pain and 22 (8.6%) a decrease in pain due to the plaster treatment. Neither pre-procedural nor post-procedural pain were significantly different between the two groups (Table II).

Subgroup analyses. VR was associated with lower anxiety levels in younger patients, females, removal of plaster, in previous plaster treatment, or in upper limb fractures (Table III). The opposing subgroups – 12 to 17 years old, males, plaster replacement, no previous treatment, method of removal, and lower limb fracture – had no significant differences between the control group and the intervention group.

Discussion

The aim of this study was to evaluate the effect of distraction by VR on the anxiety levels of children with fractures, in the plaster room. This study showed that VR significantly reduced anxiety levels during plaster treatment. The subanalyses showed that VR was especially effective in the following subgroups: five- to 11-year-olds, females, previous treatment, plaster removal, scissors only, and fractured upper limbs. However, VR was ineffective at reducing the level of pain and had no effect on the heart rate or satisfaction scores.

To our knowledge, this study is the second to investigate the effects of VR in the plaster room. A previous pilot study by Jivraj et al[13] also found that VR significantly reduced anxiety levels in children during plaster removal, but their study design and population were different. Jivraj et al[13] used a video game with a manual controller, included a smaller population of patients, and used different anxiety measurement instruments and secondary outcome measures. The differences in study design and population make it difficult to directly compare the two reports, although both have shown that VR effectively decreases the anxiety levels in children in the plaster room.

The results of our research with regard to anxiety are in line with VR studies used in other medical fields such as blood withdrawal,[9] dental care,[10] intravenous procedures,[11] and burn wound care.[12] However, in contrast with other reports, we found that VR had no significant effect on pain perception during the plaster treatment. The other studies used VR in settings where the procedure itself was painful, such as blood withdrawal[9] and burn wound care.[12] Conversely, we investigated the effect of VR during plaster removal or application, which in itself is normally not a painful procedure.

The measured heart rates showed no significant decrease with the use of VR, possibly because of the variability of the heart rate. The children in the control group were able to see the finger pulse oximeter and therefore their own heart rate, but those in the intervention group could not. The biofeedback on their heart rate could possibly have augmented the results in the control group.[19] However, most children were more focused on the plaster treatment. Moreover, biofeedback can only have an effect on children who understand how they can affect their

Table II. Primary and secondary outcomes.

Outcome	Total	p-value
Primary outcome		
Median anxiety (IQR)*		< 0.001†
Control	0.0 (0.0 to 1.0)	
Intervention	0.0 (0.0 to 0.0)	
Secondary outcome		
Median anxiety reduction (IQR)‡		0.028†
Control	0.0 (-1.0 to 0.0)	
Intervention	0.0 (-1.0 to 0.0)	
Median NRS pain before (IQR)		0.084†
Control	0.0 (0.0 to 0.0)	
Intervention	0.0 (0.0 to 0.0)	
Median NRS pain after (IQR)		0.260†
Control	0.0 (0.0 to 1.5)	
Intervention	0.0 (0.0 to 0.25)	
Mean NRS satisfaction, child (SD)		0.173§
Control	8.7 (1.0)	
Intervention	8.7 (1.4)	
Mean NRS satisfaction, parent/ guardian (SD)		0.679§
Control	9.0 (1.4)	
Intervention	8.7 (1.1)	
Mean heart rate, BPM (SD)		0.392§
Control	102.7 (18.0)	
Intervention	97.6 (16.1)	

*Post-procedural CFS.
†Mann-Whitney U test.
‡Pre-procedural CFS minus post-procedural CFS.
§Independent-samples *t*-test.
BPM, beats per minute; CFS, Children's Fear Scale; IQR, interquartile range; NRS, numerical rating scale; SD, standard deviation.

Table III. Outcomes of the subanalyses on post-procedural anxiety scores (Children's Fear Scale).

Variable	n	Median (IQR)	p-value*
Age group (yrs)			
5 to 11	155		< 0.001
Control	77	1.0 (0.0 to 1.0)	
Intervention	78	0.0 (0.0 to 1.0)	
12 to 17	100		0.134
Control	48	0.0 (0.0 to 0.8)	
Intervention	52	0.0 (0.0 to 0.0)	
Sex			
Female	120		< 0.001
Control	63	1.0 (0.0 to 1.0)	
Intervention	57	0.0 (0.0 to 0.0)	
Male	135		0.117
Control	62	0.0 (0.0 to 1.0)	
Intervention	73	0.0 (0.0 to 0.0)	
Type of treatment			
Removal	197		< 0.001
Control	97	0.0 (0.0 to 1.0)	
Intervention	100	0.0 (0.0 to 0.0)	
Replacement	58		0.156
Control	28	0.0 (0.0 to 1.0)	
Intervention	30	0.0 (0.0 to 0.3)	
Previous treatment			
Yes	184		< 0.001
Control	87	0.0 (0.0 to 1.0)	
Intervention	97	0.0 (0.0 to 0.0)	
No	71		0.055
Control	38	0.0 (0.0 to 1.0)	
Intervention	33	0.0 (0.0 to 0.0)	
Method of removal			
Scissors	161		0.002
Control	84	0.0 (0.0 to 1.0)	
Intervention	77	0.0 (0.0 to 0.0)	
Scissors and saw	94		0.051
Control	41	0.0 (0.0 to 1.0)	
Intervention	53	0.0 (0.0 to 0.0)	
Limb fractured			
Upper limb	204		< 0.001
Control	102	0.0 (0.0 to 1.0)	
Intervention	102	0.0 (0.0 to 0.0)	
Lower limb	51		0.192
Control	23	0.0 (0.0 to 1.0)	
Intervention	28	0.0 (0.0 to 0.8)	

*Mann-Whitney U test.
IQR, interquartile range.

heart rate and how this affects their anxiety level. This is very unlikely to occur in young children,[20] and moreover, the heart rate can be influenced by many other factors.

The satisfaction scores were overall very high, and no significant difference was found between the control and intervention groups. This indicates that both the parents/guardians and the children were very satisfied with the quality of their plaster treatment, and the use of VR did not further improve their level of satisfaction.

We found that in the younger age group (five to 11 years), VR caused a significant reduction in anxiety. This finding is in line with the results of Eijlers et al,[12] and can be explained by the overall higher anxiety that the younger children experience in (new) medical surroundings. Additionally, younger children have a higher level of "magical thinking" and are therefore possibly more immersed in the VR than older children.[21] During this study, we observed that the younger age group was more engrossed in the VR, but the older age group was frequently still aware of their surroundings and the procedure that was happening. The fact that children aged five to 11 years seem to benefit more from VR should be taken into account when implementing VR. Furthermore, females reported higher baseline anxiety scores and more benefit from the VR than males. This suggests that females in this study were more anxious than males.

The other subgroup analyses showed that plaster removal and a fracture in the upper limb in combination with VR were associated with reduced anxiety levels after the procedure. However, the plaster replacement, use of saw and scissors, and lower limb groups all had fewer participants than their counterparts. The smaller sample sizes of these groups might play a role in the significance of levels found. Additionally, a possible reason that the use of a saw shows no significant results is that the child can still hear the sound of the saw over the sound of the video, and can feel the saw vibrate on their skin. This can cause the child to be less distracted and thus benefit less from

VR. The use of noise-cancelling headphones may increase the level of distraction.[22]

The main limitation of this study is the median value of 0 in both groups for the main outcome. This could be due to the so-called "floor effect". Contrary to data in the literature, baseline anxiety was not so pronounced in this study population, with median baseline scores of 0.[2,3] This could underestimate the true effect of VR. As a consequence, further anxiety reduction was challenging to achieve. In addition, there could have been the possibility of influence from an external observer, the investigator, in the plaster room: along with the typical presence of an orthopaedic surgeon and a specialist in applying plaster casts, which could potentially lead to a heightened state of stress. Nevertheless, considering that the children had been notified of the intervention and the investigator was present with all the patients in the study, we presume that this was not a relevant issue.

In conclusion, we have shown that VR effectively reduces the level of anxiety in children with a fractured limb who are treated with plaster. In addition, VR proves to be most effective in the younger age group and particularly in young girls.

Take home message

- Using virtual reality as a distraction during plaster treatment significantly reduces fear among young children, particularly benefiting young girls in the plaster room.
- Research shows promising results in alleviating anxiety and enhancing the treatment experience.

Supplementary material

Table listing the frequencies of the specific fracture locations. The 255 patients included had 292 fractures in total.

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I. Koenraadt-van Oost: Data curation, Funding acquisition, Resources, Writing – review & editing.
P. Boele van Hensbroek: Conceptualization, Supervision, Writing – review & editing.
C. J. A. van Bergen: Conceptualization, Methodology, Supervision, Writing – review & editing.

Funding statement:

The authors disclose receipt of the following financial or material support for the research, authorship, and/or publication of this article: this study received financial support from the Amphia Hospital Science Fund and Amphia Innovation Fund. The equipment (Oculus Go, Oculus Quest 2 (VR

goggles) and iPads) were provided by Vrienden van Amphia, Jack Rabbit Foundation, TopOpKids, and Kiwanis.

ICMJE COI statement:
M. Poppelaars, C. van Bergen, and L. van der Water report funding for this study from Amphia (Wetenschapsfonds and Innovatie Hub).

Data sharing:
The data that support the findings for this study are available to other researchers from the corresponding author upon reasonable request.

Acknowledgements:
We are grateful to M. Mai for his contributions to the patient inclusions in this study.

Ethical review statement:
The study was approved by the MEC-U (NL75353.100.20), a recognized medical research ethics committee.

Open access funding:
The open access fee for this article was provided by the Amphia Hospital Science Fund and the Amphia Innovation Fund.

Trial registration number:
The trial was registered in the International Clinical Trials Registry Platform (ICTRP) (NL9065) on 27 November 2020.

This article was primary edited by S. P. F. Hughes.