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Preliminary effectiveness of 3D-printed orthoses in chronic hand conditions: study protocol for a non-randomised interventional feasibility study

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ABSTRACT

Introduction Hand orthoses are often provided to improve performance of activities of daily life (ADL). Yet, the manufacturing process of conventional custom-fabricated hand orthoses is a time-consuming and labour-intensive process. Even though three-dimensional (3D) printing of orthoses is a rapidly growing area that can facilitate the manufacturing process of hand orthoses, evidence on the effectiveness, costs and production time of 3D-printed orthoses in chronic hand conditions is scarce. This study aims to assess (1) the preliminary effectiveness of 3D-printed orthoses compared with conventionally custom-fabricated orthoses in persons with chronic hand conditions, (2) production time and costs of both orthoses and (3) experiences of the participants and orthotists with the manufacturing process of the 3D-printed orthosis.

Methods and analysis In this prospective non-randomised interventional feasibility study, 20 adults with various chronic hand conditions using a conventional thumb, wrist or wrist-thumb orthosis will be provided with a 3D-printed corresponding type of orthosis. Assessments will be done 2 weeks prior to the intervention and at baseline for the conventional orthosis, and at 1 month and 4 months follow-up for the 3D-printed orthosis. The primary outcome is change from baseline in ADL performance (custom short form Dutch-Flemish Patient-Reported Outcomes Measurement Information System-Upper Extremity; ADL domain Michigan Hand Outcomes Questionnaire Dutch language version (MHO-DLV)) at 4 months follow-up. Secondary outcomes include general hand function (MHO-DLV), satisfaction with the orthosis (Dutch Client Satisfaction with Device; Dutch version of the Quebec User Evaluation of Satisfaction with Assistive Technology), usability (in-house questionnaire) and quality of life (EuroQoL 5-Dimension 5-Level). Costs and production time of the conventional and 3D-printed orthoses will be prospectively recorded. Experiences regarding the manufacturing process will be obtained from participants and orthotists (in-house questionnaire).

Ethics and dissemination The Medical Ethics Committee of the Amsterdam UMC, Academic Medical Centre, has waived the requirement for ethical review of this study. Results will be disseminated through peer-reviewed journals, scientific conferences, and media aimed at a broad audience including patients.

Trial registration number NCT05320211.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Protocling the intervention will reduce variation in orthoses due to individual manufacturing preferences, and therefore, improve the internal validity.
⇒ A broad range of patient-reported outcome measures will be collected until 4 months follow-up to provide a broader view on the preliminary effectiveness of the three-dimensional (3D) printed orthoses.
⇒ Insights will be gained into the costs and production time of 3D-printed versus conventional orthotic care.
⇒ Results will be obtained in a heterogeneous sample, which increases the generalisability of results.
⇒ Selection bias can occur when especially people who are dissatisfied with their conventional orthosis or because of the coolness factor of a 3D-printed orthosis are willing to participate.

INTRODUCTION

Additive manufacturing, otherwise known as three-dimensional (3D) printing, is becoming increasingly popular in the field of orthotics, not only in manufacturing lower extremity orthoses,1 but more recently also in 3D-printing of upper extremity orthoses for chronic disabling conditions.2 In the Netherlands alone, 27 000 persons are provided with upper extremity orthoses each year,3 of which a large part includes hand orthoses.

In chronic disabling hand conditions, symptoms such as pain, muscle weakness, loss of sensibility, spasticity, and joint and/or muscle contractures are common impairments4-6 that negatively affect daily life activities.6-8 Participation and quality of life7,9 Wearing a hand orthosis to support or align a joint, restrict joint motion, or prevent or correct joint deformities can reduce pain, and improve grip and/or use of the hand in daily activities.10-13

Most people with a chronic hand condition use their hand orthosis on a daily basis,
and therefore, the orthosis must fit well, be breathable and waterproof. A 3D-printed orthosis could meet these requirements. Further, the anatomical features of the arm and hand may be obtained more accurately by 3D-scanning than with conventional casting using a plaster hand model. Also, 3D-scanning is perceived as more comfortable compared with casting by hand orthotic users. Another advantage is that the 3D-printing process eliminates several steps from the conventional manufacturing process of custom-fabricated orthoses, and is therefore less time-consuming.

Yet, although 3D-printing has several promising advantages and 3D-printed hand orthoses are increasingly applied within routine care, evidence for the effectiveness, and production time and costs of 3D-printed orthoses in chronic hand conditions is scarce. Our recent scoping review on this topic identified only 12 studies on chronic hand conditions. These were mostly case reports/case series (n=8), and of the four clinical trials, only one was of high methodological quality. Furthermore, it was noticed that only one clinical trial reported on the performance of activities of daily living (ADL), while the main goal for prescribing a hand orthosis is to support the hand during ADL. Also, in none of the clinical trials, an outcome on costs was included.

The lack of knowledge on the effectiveness of 3D-printed orthoses on ADL performance and its costs, in combination with the promising findings of our case series that showed that production time of 3D-printed orthoses was half that of conventional orthoses and satisfaction with both orthoses similar, encourage further study of the cost-effectiveness of 3D-printed orthoses in chronic hand conditions. However, before setting up a full-blown cost-effectiveness study, insight into the preliminary effectiveness of 3D-printed orthoses on daily-life functioning and cost reductions is needed. To gather this information, we set up an interventional feasibility study. According to Bowen’s feasibility framework, we will evaluate the following focus areas of feasibility: limited efficacy testing, practicality and acceptability. The aims of our study are to (1) assess the preliminary effectiveness of 3D-printed orthoses for permanent use for improving ADL performance, general hand function, usability and quality of life compared with conventionally custom-fabricated orthoses in persons with chronic hand conditions; (2) record production time and costs of both interventions and (3) assess satisfaction with the orthosis and experiences of the participants and orthotists with the manufacturing process of the 3D-printed orthosis.

**METHODS AND ANALYSIS**

**Study design**

This is a prospective non-randomised interventional feasibility study to evaluate the preliminary effectiveness of 3D-printed hand orthoses, together with the assessment of costs, production time and experiences by users and orthotists. A within-subjects design will be used, meaning that the 3D-printed orthosis (intervention) will be compared with the participants’ current conventional orthosis (control condition at baseline). Participants will be evaluated four times within a 5-months period: 2 weeks prior to the intervention (T1), directly preintervention (baseline, T2) and after 1 month (T3) and 4 months (T4) of follow-up (figure 1). Amsterdam University Medical Centres (UMC), location Academic Medical Centre (AMC), is the initiator of the study. The study protocol is based on the items recommended by Standard Protocol Items: Recommendations for Interventional Trials (online supplemental file 1). The Dutch informed consent form that will be used in the study is included as online supplemental file 2. The study is prospectively registered at ClinicalTrials.gov (identifier NCT05320211).

**Setting**

The intervention will be provided by one of three branches of OIM Orthopedie (OIM Noordwijkhout, OIM Zwolle and OIM Breda, The Netherlands). Two weeks prior to the start of the intervention (T1), the informed consent procedure and screening assessment will be performed at the Department of Rehabilitation Medicine of the Amsterdam UMC. All other assessments (T2–T4) include questionnaires, which will be sent to the participants digitally. If necessary, a reminder will be sent after 1 week to participants who did not fill in the questionnaire.

**Study population**

For this study, recruitment started in March 2022 and the first patient was included on 12 April 2022. In total 20 adults will be included with a stable, chronic hand condition due to a neuromuscular disease, neurological disorder, musculoskeletal disorder or injury. Participants will be recruited from the database of OIM Orthopedie. Eligible persons will be invited to take part in the study by means of an information letter, including a response
card. If a person is willing to participate, a screening visit will be planned to obtain written informed consent and to check the inclusion and exclusion criteria by the investigator (a certified hand therapist). The inclusion criteria are as follows: (1) aged ≥18 years and (2) ≥2 years wearing a conventional circular thumb orthosis (TO), wrist orthosis (WO, including wrist immobilisation or wrist and thumb base immobilisation), or wrist-TO (WTO) for permanent use. Exclusion criteria are as follows: (1) currently wearing a 3D-printed orthosis, (2) a silver splint for the thumb and/or wrist, (3) an orthosis prescribed for a dysfunctional hand, (4) a broken orthosis, (5) a night orthosis and (6) insufficient mastery of the Dutch language.

### Sample size

This feasibility study is not powered to determine the effectiveness of 3D-printed orthoses. However, 20 participants are considered a sufficiently large sample to evaluate the preliminary effectiveness and to get an impression of the effect size and variance of the included outcomes. These results can be used as input for choice on design and sample size calculation of future trials, aimed at assessing the effectiveness of 3D-printed orthoses with statistical significance.

Since the source population of OIM Orthopedie consists of 400 persons, we anticipate that at least 20 participants will give their informed consent to participate within the timeline of the study.

### Study procedures

After receiving the participants’ informed consent, outcomes with the participants’ conventional orthosis will be assessed (at T1) and reassessed 2 weeks later (at T2). Subsequently, the intervention will start. One week after delivery of the 3D-printed orthosis, participants will be contacted by the investigator to check whether the orthosis is used in daily life and fits well (ie, no pressure points, no skin irritations and adequate immobilisation/stiffness of the orthosis). If these requirements are met, measurements will be scheduled after 1 month (T3) and 4 months follow-up (T4). If the fit of the 3D-printed orthosis is not satisfactory, the orthosis will be revised, after which the follow-up period starts. All study outcomes will be inventoried by questionnaires, which will be sent digitally using an electronic data capture system (Castor EDC, Amsterdam, the Netherlands).

### Intervention

The 3D-printed orthoses will be compared with conventional custom-fabricated orthoses (referred to as conventional orthoses). The 3D-printed orthosis will be the same type as the conventional orthosis worn by the participant.

#### Conventional orthoses

Conventional orthoses in our study may include circular TO, WO and WTO of all kinds of materials, like resin, erkeflex, leather, silicone. To manufacture the conventional orthosis, a plaster cast of the participant’s affected hand and forearm was made. From this cast, a plaster hand model was created. Based on this model, the orthosis was manufactured as described in Oud et al. After fabrication, fitting and alignment of the orthosis were checked, and, if necessary, the orthosis was corrected prior to delivery.

#### 3D-printed orthoses

3D-printed orthoses will include circular TO, WO and WTO made of thermoplastic polyurethane (TPU) (figure 2). For fitting of the 3D-printed orthoses, the participants’ affected hand and forearm will be scanned with a calibrated iPad by an experienced orthotist using the Spentys app (Spentys, Vorst, Belgium). Participants will be asked to keep their arm in the correct position without moving for a maximum of 3 min. Would the participant not be able to maintain this position, an assistant will support the arm. If needed, the 3D scan will be postprocessed, for example, for areas of the affected arm requiring pressure relief. Based on the 3D scan and presigned standardised scripts, the orthosis will be designed digitally by Spentys, printed in TPU and coated for water resistance (ZiggZagg, Aalter, Belgium). The thickness will be 2.5 mm for the TO and 4 mm for the WO and WTO. The offset for the WTO and TO will be 0.4 mm, whereas no offset will be used for the WO. In case the 3D-printed orthosis requires deviation from the presigned model script (eg, length or thumb position), the 3D-printed orthosis will be more personalised. For closure of the WTO and WO, velcro straps will be added on the dorsal side of the orthosis, while the TO can be closed using an integrated closing system. Before delivery of the orthosis, fitting and alignment will be checked.

Both the conventional and 3D-printed orthoses have been or will be provided through the Health Insurance Regulations.

### Compliance

To conduct the 3D intervention uniformly across the three branches of OIM Orthopedie, all participating orthotists will be thoroughly trained. Each orthotist will be informed about (1) the aim of the study, (2) the three eligible types of orthoses, (3) the steps needed to manufacture each orthosis type, (4) use of the iPad (including calibration) and Spentys app, (5) the information
required to document in the order for Spentys and (6) how to record time of each manufacturing step.

**Outcome measures**
In selecting outcome measures for this study and for a future cost-effectiveness study, different components of the International Classification of Functioning, Disability and Health are taken into account. An overview of all outcomes per measurement time point is given in table 1.

**Limited efficacy testing**

**ADL performance**
The primary study outcome is ADL performance, assessed with a custom short form created from the Dutch-Flemish Patient-Reported Outcomes Measurement Information System-Upper Extremity (DF-PROMIS-UE) item bank V.2.0. Of the 46 described activities, 25 activities were selected for this study (online supplemental file 3). Participants will rate how easily they can perform each activity on a 5-point scale, ranging from ‘without any difficulty’ (score 4 or 5) to ‘unable to do’ (score 1). For each activity, the question was added whether participants use their orthosis for that specific activity. The total score will be expressed as a T-score, which is a standardised score, with 50 representing the average score of the US general population and 10 being its SD.19 The PROMIS-UE was originally developed in English,20 and has been translated into Dutch-Flemish and cross-culturally validated.19 21

ADL performance will also be assessed with the ADL domain of the Michigan Hand Outcomes Questionnaire Dutch language version (MHQ-DLV), containing 17 items rated on a 5-point scale, ranging from ‘not difficult at all’ (score 1) to ‘very difficult’ (score 5). The MHQ has been shown a reliable and valid instrument for measuring hand functioning in patients with rheumatoid arthritis, osteoarthritis and stroke.22–25

**As secondary outcomes**, general hand function, usability, quality of life, production time and costs, and participants’ and orthotists’ experiences will be assessed.

**General hand function**
General hand function will be measured with the MHQ-DLV. In addition to ADL performance, the MHQ-DLV assesses overall hand function (10 items), work performance (5 items), aesthetics (8 items), satisfaction (12 items) and pain (5 items). Per domain, a sum score ranging from 0 to 100 is obtained. To calculate the total MHQ-DLV score, the mean score of the six domains will be calculated. A higher total score indicates better results (ie, better performance, higher satisfaction and less pain).

**Table 1** Overview of measurements at the different assessment moments

<table>
<thead>
<tr>
<th></th>
<th>Conventional orthosis</th>
<th>3D-printed orthosis</th>
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<tr>
<td></td>
<td>T1</td>
<td>T2</td>
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<tr>
<td><strong>Limited efficacy testing</strong></td>
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<tr>
<td>Primary outcome</td>
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<tr>
<td>ADL performance</td>
<td>DF-PROMIS-UE x</td>
<td>x</td>
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<tr>
<td>ADL performance</td>
<td>MHQ-DLV</td>
<td>x</td>
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<tr>
<td>Secondary outcomes</td>
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<tr>
<td>General hand function</td>
<td>MHQ-DLV</td>
<td>x</td>
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<tr>
<td>Usability</td>
<td>In-house questionnaire</td>
<td>x</td>
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<tr>
<td>Quality of life</td>
<td>EQ-5D-5L</td>
<td>x</td>
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<tr>
<td><strong>Practicality</strong></td>
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<tr>
<td>Production time</td>
<td>Prospectively assessed</td>
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<tr>
<td>Production costs</td>
<td>Administration records</td>
<td></td>
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<tr>
<td>No of visits</td>
<td>Administration records</td>
<td></td>
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<tr>
<td><strong>Acceptability</strong></td>
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<tr>
<td>Satisfaction</td>
<td>D-QUEST</td>
<td>x</td>
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<td></td>
<td>D-CSD</td>
<td>x</td>
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<tr>
<td>Participants’ and orthotists’ experiences</td>
<td>In-house questionnaire</td>
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<tr>
<td><strong>Additional outcomes</strong></td>
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<tr>
<td>Demographics</td>
<td>Intake form</td>
<td>x</td>
</tr>
<tr>
<td>Clinical data</td>
<td>Intake form</td>
<td>x</td>
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<tr>
<td>Adverse events</td>
<td>AE form</td>
<td>x</td>
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</tbody>
</table>

ADL, activities of daily life; AE, adverse event; 3D, three dimensions; D-CSD, Dutch Client Satisfaction with Device; DF-PROMIS-UE, Dutch-Flemish Patient-Reported Outcomes Measurement Information System-Upper Extremity; D-QUEST, Dutch version of the Quebec User Evaluation of Satisfaction with Assistive Technology; EQ-5D-5L, EuroQol 5-Dimension 5-Level; MHQ-DLV, Michigan Hand Questionnaire Dutch language version.
Usability
To evaluate usability, an in-house questionnaire will be used to assess the achievement of personal goals for the conventional orthosis 2 weeks prior to the intervention and for the 3D-printed orthosis at 1 month and 4 months follow-up.

Quality of life
Quality of life will be assessed with the EuroQol 5-dimension 5-level (EQ-5D-5L) questionnaire.26 27 Five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression), with one item per dimension, will be scored on a 5-point scale. Further, participants will be asked to give a 0–100 VAS score for their own health status. The EQ-5D-5L is a widely used generic questionnaire, which is reliable and valid in a broad range of populations.28

Practicality
As outcomes of practicality, we will assess production time and costs of both interventions. For the assessment of production time of the conventional orthoses, OIM Orthopedie will newly manufacture the three types of orthoses evaluated in this study, and prospectively record the time (min; sec) needed for each step of the manufacturing process. Production time for the 3D-printed orthosis will be prospectively measured for each step during the intervention. Costs of the conventional orthoses will be retrospectively inventoried from the administration records of OIM Orthopedie, and costs of the 3D-printed orthoses will be prospectively assessed. Furthermore, during the intervention, the number of visits needed to deliver the 3D-printed orthosis will be counted. The number of visits required for the conventional orthosis will be counted from the records of OIM Orthopedie.

Acceptability
Satisfaction
Satisfaction with the orthosis will be assessed with the Client Satisfaction with Device (CSD) questionnaire, containing nine items rated on a 5-point Likert scale ranging from 0=strongly disagree to 4=strongly agree, resulting in a sum score of 0–36.29 Since the CSD is not yet available in Dutch, we translated the CSD for the Dutch population. Further, the device part of the valid and reliable Dutch version of the Quebec User Evaluation of Satisfaction with Assistive Technology (D-QUEST) will be used to assess satisfaction with the orthosis.30 31 The device part consists of eight questions about characteristics of the device, in this case the orthosis, all scored on a 5-point scale (from ‘not satisfied at all’ to ‘very satisfied’). The sum score ranges from 8 to 40, with higher scores indicating better satisfaction.

Experiences
Participants’ and orthotists’ experiences with regard to the procedure of scanning, fitting and delivery of the 3D-printed orthosis and the time needed for the intervention will be assessed by scoring seven questions on a 5-point scale (from ‘not satisfied at all’ to ‘very satisfied’). Further, the pros and cons of manufacturing the 3D-printed orthosis compared with the conventional orthosis will be inventoried in both groups with open-ended questions.

Additional outcomes
Sociodemographics (eg, age, gender) and clinical characteristics (eg, reason of hand orthosis use, time since wearing an orthosis, frequency of orthosis use) will be recorded at the screening visit, as well as orthotic properties (eg, type and material) of the conventional orthosis. Pros and cons of both orthoses will be inventoried with open-ended questions, and for the 3D-printed orthosis, we will also monitor adverse events.

Statistical analysis
Sociodemographics, clinical characteristics, orthosis properties and adverse events will be summarised with appropriate descriptive statistics. Approximately normally distributed continuous variables will be expressed as means and SDs; non-normally distributed data and ordinal data as medians, ranges and IQRs (25th–75th percentiles); and categorical data as percentages.

Limited efficacy testing
For analysing the preliminary effectiveness, we will employ (generalised) mixed models to accommodate repeated measurements within individuals. Choice of link function (eg, logit link) will be determined by the distribution of the response variable, possibly after dichotomisation, and we will consider time since baseline as categorical covariate. Reliability of the DF-PROMIS-UE and MHQ for assessing ADL performance prior to intervention will be assessed by Bland-Altman analysis. By appropriate model specification of repeated measurements, the scores of the DF-PROMIS-UE and MHQ-DLV prior to intervention will be pooled (mean T1/T2) and compared with scores after the follow-up of the 3D-printed orthoses (T3 and T4). Also, the short-term (T3) ADL performance scores will be compared with the mid-term (T4) scores via appropriate recoding of the reference category.

In addition, Hedges’ g will be calculated for the outcomes of each questionnaire to determine which one is most responsive to the intervention. Furthermore, the variation around the mean differences will be explored in descriptive analyses to gain insight into the heterogeneity in effects in relation to patient characteristics. While the sample size does not allow formal assessment of effect modification, it is relevant to already consider possible dependency of effectiveness on characteristics at the patient or orthosis level. These insights can serve as input in design and power calculations of a future trial.

Practicality
Differences in costs and production time between the 3D-printed orthoses and the conventional orthoses will be analysed with appropriate parametric or non-parametric test statistics, that is, paired sample t-tests or Wilcoxon
signed-rank tests if data are not-normally distributed. The number of visits will be analysed with descriptive statistics.

Acceptability

Generalised mixed models will also be used to compare the D-CSD and D-QUEST satisfaction scores of both orthoses for the different measurement time points (T1/ T2 compared with T3 and T4; and T3 compared with T4). For the D-QUEST, only one baseline measurement will be available and pooling is therefore not needed.

Also, Hedges’ g will be calculated for the outcomes of each questionnaire to determine which of the two questionnaires is most responsive to the intervention.

Experiences of participants and orthotists with respect to the time window of the 3D intervention and satisfaction with the treatment process will be analysed with descriptive statistics.

Missing values will not be imputed and individuals with missing data will not be discarded. For all analyses, a p<0.05 will be considered significant.

Patient and public involvement

Two patient representatives were actively involved in the preparation of this study by providing feedback on the study protocol. Suggestions were incorporated in the study protocol. The participants will be informed about the results of the study by mail and a newsletter.

Furthermore, study results will be disseminated through publication on websites (eg, OIM Orthopedic, rheumatoid arthritis patient union (SRPN)) and social media (eg, LinkedIn), ensuring study results are communicated to the participants and also to a general wider community.

DISCUSSION

We have presented the design of a feasibility study on limited efficacy testing, practicality and acceptability of 3D-printed orthoses for permanent use compared with conventionally custom-fabricated orthoses in persons with chronic disabling hand conditions.

The study has several strengths. First, standardised scripts for the three types of orthoses will be used, and the orthotists will be trained for providing the 3D-intervention. Protociling the intervention will reduce variation in orthoses due to individual manufacturing preferences, and therefore, this will improve the internal validity. Second, since the three types of orthoses addressed in our study are most commonly applied in chronic hand conditions and worn by a heterogeneous population with a diversity of diagnoses, the external validity will be high. Third, a broad range of patient-reported outcomes on consecutive time points before and after orthotic treatment will be collected. The main focus will be on performance of daily activities, which has not been investigated before. For assessing satisfaction with the orthosis, a questionnaire specifically about satisfaction with the orthosis was searched for and translated for this study (D-CSD). Furthermore, besides evaluating orthosis effectiveness and satisfaction, data on production time and costs will be inventoried, which are important aspects when implementing a new intervention in clinical practice. Finally, including a 4-month follow-up will not only provide information about the mid-term results on effectiveness of and satisfaction with the 3D-printed orthosis, but also about possible mid-term adverse events.

Our study also has some limitations. First, the sample size is not motivated by considerations of statistical significance. Instead, the sample size of 20 participants serves to get a good impression of the feasibility and potential effectiveness of 3D-printed orthoses, which can be used as input for choice on design and adequate sample size calculation for a full-blown cost-effectiveness study. Second, selection bias could occur when especially people who are dissatisfied with their conventional orthosis or due to the coolness factor of 3D-printed orthoses are willing to participate. Third, since most participants are dependent on their orthosis for daily functioning, no wash-out period will be applied. This could induce the risk of carryover effects. Instead, as suggested by Sibbald and Roberts, we will restrict the outcome measurements to the latter part of the wearing period of the 3D-printed orthosis, that is, at 1 month (T3) and 4 months (T4) after delivery of the 3D-printed orthosis. This way, we expect that carryover effects will be minimised. In a future cost-effectiveness study, with a longer time frame, a cross-over design can be considered where participants both wear a 3D-printed and a conventional orthosis in a randomised order, to (further) limit carryover effects.

Ethics and dissemination of results

Since the intervention is part of routine care and the questionnaires are not burdensome for the participants, the requirement for ethical review of the study protocol under the Medical Research Involving Human Subjects Act in the Netherlands was waived by the medical ethics committee of the Amsterdam UMC, location AMC (2 September 2021). The study will be performed in accordance with good clinical practice guidelines. When patients sign their informed consent, they will receive a participant ID, which will be coupled to all the data collected. Only persons involved in the study have access to paper forms and digital files related to the study. Insurance has been taken out for participation of patients in the study. After completion of the study, positive as well as negative results will be submitted to a peer-reviewed journal and presented at national and international scientific conferences. The responsibility for publication and presentation belongs to the investigators. Only those investigators making a significant contribution to the study design and/or the collection, analysis or interpretation of the data will be eligible for authorship. No restrictions regarding the public disclosure and publication of the research data have been, or will be made, by the funders.

Anonymised individual participant data (IPD) and metadata will be made available to third parties via
Figsshare. Other anonymised IPD and documents will be made available on request including data analyses codes such as SPSS syntaxes or R scripts. IPD will be made available, provided that patients give their informed consent for this, following publication of the project results without end date, for investigators who provide a methodologically sound proposal for analyses with the aims defined in the proposal.

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Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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Provenance and peer review Not commissioned; externally peer reviewed.

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