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Bracing Adolescent Idiopathic Scoliosis (BASIS) study – night-time versus full-time bracing in adolescent idiopathic scoliosis: study protocol for a multicentre, randomized controlled trial

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Aims

Scoliosis is a lateral curvature of the spine with associated rotation, often causing distress due to appearance. For some curves, there is good evidence to support the use of a spinal brace, worn for 20 to 24 hours a day to minimize the curve, making it as straight as possible during growth, preventing progression. Compliance can be poor due to appearance and comfort. A night-time brace, worn for eight to 12 hours, can achieve higher levels of curve correction while patients are supine, and could be preferable for patients, but evidence of efficacy is limited. This is the protocol for a randomized controlled trial of 'full-time bracing' versus 'night-time bracing' in adolescent idiopathic scoliosis (AIS).

Methods

UK paediatric spine clinics will recruit 780 participants aged ten to 15 years-old with AIS, Risser stage 0, 1, or 2, and curve size (Cobb angle) 20° to 40° with apex at or below T7. Patients are randomly allocated 1:1, to either full-time or night-time bracing. A qualitative sub-study will explore communication and experiences of families in terms of bracing and research. Patient and Public Involvement & Engagement informed study design and will assist with aspects of trial delivery and dissemination.

Discussion

The primary outcome is 'treatment failure' (Cobb angle progression to 50° or more before skeletal maturity); skeletal maturity is at Risser stage 4 in females and 5 in males, or 'treatment success' (Cobb angle less than 50° at skeletal maturity). The comparison is on a non-inferiority basis (non-inferiority margin 11%). Participants are followed up every six months while in brace, and at one and two years after skeletal maturity. Secondary outcomes include the Scoliosis Research Society 22 questionnaire and measures of quality of life, psychological effects of bracing, adherence, anxiety and depression, sleep, satisfaction, and educational attainment. All data will be collected through the British Spine Registry.

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Introduction

Background. Scoliosis is a lateral curvature of the spine with associated vertebral rotation. It can cause considerable distress due to appearance.[1] Curve size is most commonly measured using the Cobb angle, and 0.2% to 0.5% of the population aged under 16 years will have a Cobb angle over 20°.[2] The majority of curves begin in early adolescence, have no identifiable underlying cause, and are referred to as adolescent idiopathic scoliosis (AIS). Growth is the major factor for worsening; curves that reach 50° often require surgery, which can carry substantial risks to the patient and costs to the NHS (£27,206, 2023/24 NHS Tariff).[3]

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There are treatment options for reducing the risk of curve progression during growth, including scoliosis-specific exercises (although evidence is lacking)[4] and bracing, which seeks to hold the spine in the best possible corrected position to prevent curve progression. There is high-quality evidence from a previous clinical trial to support full-time bracing (FTB) versus observation alone.[5] While efficacy of bracing is established, compliance and acceptability to patients are a concern, with significant psychological impact.[6]

An alternative is a brace only worn at night (NTB), which could improve quality of life and the psychological effects of bracing, due to not needing to wear the brace during the day, and at school, while still providing effective correction to the curve. However, evidence is limited to small cohort studies, calling for further trials in this area.[7]

Rationale. In the UK, instrumented scoliosis correction for AIS increased by 8% in the six years before COVID-19 (2014/15 1,240; 2019/20 1,343; unpublished Hospital Episode Statistics (HES) data). Given the complications of surgery,[8] it is imperative that acceptable and efficacious bracing techniques are identified in order to attempt to prevent the progression of scoliosis to levels that could be considered for surgery. In addition, the COVID-19 pandemic resulted in a substantial increase to waiting times for elective surgery, which has not yet improved, and it is more important than ever to prevent AIS surgery wherever possible.

Families tell us that they would prefer the NTB over the FTB, but NTB currently is not available on the NHS due to a lack of evidence for its effectiveness. The proposed study addresses four of the top 12 priorities set in 2017 by the James Lind Alliance partnership for scoliosis (priority 1: "strategies to avoid surgery", priority 2: "how does scoliosis treatment affect quality of life?", priority 5: "how likely is the scoliosis to get worse over time?", and priority 7: "what type of brace (e.g. rigid or dynamic) is most effective?").[9]

Recent systematic reviews have shown that for FTB, a low in-brace correction has the strongest evidence to predict treatment failure, especially if this is less than 25%.[10] For NTB, patients with flexible curves who are more skeletally mature (Risser 1 or 2) seem to do better.[11] However, more recent papers suggest Risser stage may not be predictive of success,[12] and that initial curve magnitude may be predictive.[13] Braces designed for night-time treatment generally provide greater levels of in-brace correction than braces designed for full-time treatment. Currently, the evidence for in-brace correction predicting success in NTB is inconclusive.

Aims and objectives. The aim of BASIS is to establish whether NTB is non-inferior to FTB in preventing treatment failure (curve progression to 50° or more in children with AIS before skeletal maturity). An additional aim is to establish whether NTB is superior to FTB in terms of patient quality of life and acceptability. The study objectives are 1) to determine if NTB is not inferior to FTB in reducing the risk of treatment failure (curve progression to 50° before skeletal maturity); 2) to determine if there is a difference in anxiety, depression, and quality of life between NTB and FTB; 3) to determine the patients' and parents' experience of and satisfaction with the braces; 4) to determine the longer-term effects of bracing on quality of life and curve progression up to two years after skeletal maturity; and 5) to evaluate the relative cost-effectiveness of NTB compared to FTB.

Methods

Trial design. BASIS is a multicentre, prospective, parallel group, pragmatic, non-blinded, randomized controlled non-inferiority trial. An economic evaluation is also included. An 18-month internal pilot phase will assess feasibility. The trial is registered with International Standard Randomized Controlled Trial Number (ISRCTN) as ISRCTN63247077.

Study setting. The trial will be conducted in a minimum of 19 hospitals in the UK who will identify patients with AIS through outpatient clinics.

Study participants. In order to be eligible for BASIS, patients must be aged between ten and 15 years; have a diagnosis of AIS (based on no other cause from the patient history and a normal neurological examination or normal MRI); Risser stage 0, 1, or 2; curve size (Cobb angle) between 20 to 40°; and curve apex at or below T7.

Patients are ineligible if they have had previous spinal bracing or spinal surgery, and/or the patient or parent is unable to adhere to trial procedures or complete required follow-up.

Sample size. A previous trial, BrAIST,[5] showed that 28% of braced patients experienced treatment failure and progressed to 50° or more before skeletal maturity, so assuming this level of treatment failure for the FTB group, with a non-inferiority margin of 11%, 90% power, 2.5% one-sided significance level, and 10% attrition, the study will require 780 participants (390 per group). This margin was chosen for BASIS, in conjunction with parents, patients, and paediatric spinal surgeons who said there is likely to be considerable functional and psychological benefit from not wearing braces during the daytime.

Participant recruitment. At or soon after the clinic visit, eligibility will be confirmed and patient information provided through signposting to the study website, which contains all trial information including animations to explain the study.[14] The website has been co-produced with patients and their families. Families will be given time to consider participation, and informed consent will be taken online; both parental consent and participant assent must be obtained for the patient to be able to take part.

Patients who do not wish to participate will be asked for their reasons, if they are prepared to share these.

Randomization and blinding. Once consent has been acquired and baseline measures are complete, the patient will be randomized to either the treatment arm (NTB) or the control arm (FTB) on a 1:1 basis, using a web-based randomization system. Randomization uses minimization based on centre, skeletal maturity (Risser stage 0, 1, or 2), and curve size (20° to 30°, 31° to 40°). Due to the nature of the interventions, patients, parents, and clinical staff will be unblinded.

Interventions. All patients will attend an appointment with the orthotist for brace measurement prior to bespoke design and manufacture of the brace. Patients will return for brace fitting, ideally within 12 weeks of screening to reduce the risk of curve progression before bracing, and minor adjustments can be made to optimize the brace. Patients will have an in-brace radiograph within six weeks of each new brace being fitted, standing for FTB and supine for NTB, to ensure good curve correction. Orthotics follow-up will occur as per standard practice, but at a minimum of every six months to align with the study protocol.

Braces will be renewed when required due to growth of the child. When a new brace is needed, the above process will be followed; bracing will continue until the patient reaches skeletal maturity, or until surgery is required. At this point, bracing can be discontinued.

Crossover from NTB to FTB will be discouraged, but is permitted if clinically appropriate. Switching from FTB to NTB is not permitted, as NTB is not currently available on the NHS. Other care such as physiotherapy is permitted alongside the trial, however surgery will not be offered unless the curve reaches 50°.

Full-time bracing. A FTB corrects the spinal curve(s) as much as possible while allowing for patient tolerance to prolonged wear during the day and night.

There are many different designs of FTB being used within the UK. There are two basic types of FTB: symmetrical thoracolumbosacral orthosis (TLSO), or asymmetrical braces which are designed using digital scanning and CAD/CAM plus modelling. The measurement and design of the FTB will be chosen by the orthotist and spinal surgeon based on current practice. The method for measurement, design, and the brace type will be recorded.

FTBs are prescribed for 20 to 24 hours a day, as recommended by The International Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT) guidelines.[15]

Night-time bracing. NTBs work on the same principles of action as FTBs, i.e. both brace types work through correction of the spine shape through externally applied forces to modulate growth. However, the design of a NTB is subtly different to that of a FTB.

Individual centres will select which NTB they will use within the trial, but this must be CAD/CAM-designed, as these braces are replacing older measurement techniques.[16,17] Available choices are the CMP night brace (The SpineCorporation Ltd, UK), or the Providence brace (Spinal Technology, USA); or, if sites have the equipment and skills locally to produce their own CAD/CAM NTB, this will be permitted after initial assessment and training. NTBs are prescribed for eight to 12 hours a day, as recommended by SOSORT guidelines.[15]

Monitoring compliance. Adherence to brace treatment will be measured using a temperature sensor (iButton DS1925; Maxim Integrated, USA) inserted into each brace (FTB and NTB). The iButton is set to record temperature every ten minutes. Data will be downloaded and will allow monitoring of adherence for the whole duration of bracing. Participants and their parents will be aware the sensor is there, but will not be given the adherence data. Clinical teams will also be blinded to adherence data.

Staff training. Orthotists will be trained in the provision of their preferred NTB, and a training discussion will be provided for those producing their own NTBs. Specific training will be given to orthotists on fitting the compliance sensors into the braces, to ensure consistency in positioning between patients, sites, and brace type.

Outcomes

Primary outcome. The primary outcome is defined as curve progression to 50° or more (treatment failure) before skeletal maturity (defined as Risser stage 4 in girls and Risser stage 5 in boys). Treatment success is a curve less than 50° at skeletal maturity.

A Radiological Adjudication Committee (RAC) will review patients considered to have reached the primary outcome (either success or failure as described above). If a curve measures 50° or more at the same visit that skeletal maturity is reached, the patient will be recorded as having progressed to 50° or more before skeletal maturity.

In order to coordinate RAC review, radiographs are transferred from each site to the Sponsor site via Image Exchange Portal (IEP). A member of the research team at the Sponsor site will then download images and anonymize these before coordinating RAC review.

Secondary outcomes. There are a number of secondary outcomes which will be collected at baseline, and at each follow-up (every six months while in brace, then at one and two years after skeletal maturity), where relevant (i.e. brace specific questionnaires are only completed while in brace).

Patient-reported outcomes. The following will be collected throughout the study unless stated otherwise: 1) Scoliosis Research Society-22 questionnaire;[18] 2) paediatric health-related quality of life, measured using the CHU9D;[19] 3) Bad Sobernheim Stress Questionnaire

(BSSQ),[20] a brace-specific questionnaire assessing the psychological effects of bracing; 4) Revised Children's Anxiety and Depression Scale (RCADS 25);[21] 5) PROMIS Paediatric Sleep Disturbance Short Form 4 a;[22] 6) PROMIS Paediatric Sleep Related Impairment Short Form 4 a; 7) Modified Client Satisfaction with Device module of the Orthotics and Prosthetics Users' Survey (CSD-OPUS);[23] 8) educational information assessed using a bespoke questionnaire after GCSE results; and 9) BAPQ score – Brace Adherence Prediction Questionnaire – a de novo questionnaire completed prior to randomization and at six-month follow-up.

Parent questionnaires**.** Non-validated bespoke questionnaires, at all timepoints unless stated otherwise, will be used to collect information on patient costs, resource use, and school attendance during bracing.

Clinical outcomes. The following will be collected throughout the study unless stated otherwise: radiological measures from out-of-brace spinal radiographs: Cobb angle, curve type, curve apex, Risser stage, in-brace Cobb angle, frontal plane balance, apical vertebral rotation, apical vertebral translation; in-brace correction, measured for all new braces as the percentage Cobb angle correction in-brace compared with out-of-brace; details of any surgery for scoliosis correction, other treatments prescribed to treat scoliosis, e.g. scoliosis-specific exercises, treatment switching; adverse events; and brace compliance, assessed using the temperature sensor (collected only during bracing).

Before randomization, patients will be asked if they have a preference for which brace they would want. Patients will also be asked at the first six-month follow-up how much they have been wearing their brace (average hours per day).

Participant schedule. Participants will be followed up every six months following randomization, while they are receiving brace treatment. After skeletal maturity, patients are followed up at one and two years, unless they have surgery, where they will be followed up at eight weeks, one year, and two years post-surgery. There is a protocol-permitted two-month window to complete each follow-up.

Due to the pragmatic nature of this study, participants should continue to attend any routine clinical appointments that are outside of the study visit schedule. Table I indicates the overall trial assessment schedule.

Data management and analysis

Data collection. Participant and parent questionnaires and clinical data will be collected directly onto the study database hosted on the British Spine Registry (BSR). Questionnaires will be sent to the parent's email address, with consent, at the scheduled timepoints to be completed electronically; paper copies, or access at a clinic visit, are available as a back-up option.

Participant retention. The study database, and site staff, can send questionnaire reminders if these have not been completed. A participant prize draw runs every two months, and those participants who have completed a full questionnaire pack since the previous draw are entered. Participant newsletters are produced during the trial, which are sent to all current participants, and are made available on the study website. These strategies are all intended to try and minimize missing data.

Participants may wish to withdraw from study treatment, or there may be a clinical need to withdraw the participant, such as development of a medical comorbidity which prevents further brace treatment. Withdrawals will be recorded, with accompanying reasons if provided. Any data collected up to the point of withdrawal will be retained and used in the final analysis. If a patient chooses to withdraw from the study, they will be asked if they are happy for the study team to use their routinely collected data in order to inform the primary outcome.

Participants will be considered lost to follow-up if they fail to attend two study visits in a row and do not complete the corresponding questionnaires. All reasonable efforts will be made to contact the participant and parent before considering a participant as lost to follow-up.

Statistical analysis plan and health economics analysis plan. Full details of the planned analyses are outlined in a statistical analysis plan (SAP) and a health economics analysis plan (HEAP). The SAP will be finalized prior to analysis for the internal pilot, and the HEAP will be finalized prior to the end of data collection.

Statistical analysis. The trial will be analyzed and reported according to CONSORT guidelines for non-inferiority trials.[24] Non-inferiority for the primary outcome – treatment failure – will be declared if the two-sided 95% confidence interval (CI) (equivalent to a one-sided 97.5% CI) for the risk difference in the event rate of treatment failure between the NTB group and the FTB group does not exceed 11%. The analysis will be completed using a generalized linear model with binomially distributed response and identity link,[25] adjusted for baseline covariates (centre, skeletal maturity Risser stage 0, 1, or 2, and Cobb angle). This will be conducted on both an intention to treat (ITT) population and per protocol (PP) basis. The adjusted differences in failure rates, along with 95% CIs, will be presented.

All secondary outcomes will assess superiority of the NTB compared to the FTB on the ITT population. Patient-reported outcomes will be compared between treatment groups, using mixed-effects linear regression with centre as a random effect, baseline and stratification variables as fixed effects, and the timepoints as both fixed and random effects. Continuous radiological measures will be compared in the same way, and categorical radiological measures using mixed-effects logistic regression and the same independent variables.

Table I. Study assessment schedule.

	Phase 1 (pre-skeletal maturity)			Phase 2 (2 yrs post skeletal maturity)	
Variable	**Screening**	**Baseline/randomization**	**Every 6 mths, until skeletal maturity**	**12 mths post skeletal maturity**	**24 mths post skeletal maturity**
Clinical					
Screening form/log (baseline visit)	MN/IP	-	-	-	-
Eligibility form	MN	-	-	-	-
Informed consent form	E	-	-	-	-
Demographics (age, sex, diagnosis, medical history, medication)	MN	-	-	-	-
Height, weight	IP	-	IP	IP	IP
Cobb angle, Risser stage	MN (pre-randomization)		CT/RAC	CT/RAC	CT/RAC
Additional radiological measures (curve type, curve apex etc)	CT	-	CT	CT	CT
Need for surgery	-	-	MN	MN	MN
In-brace correction	-	CT (0 to 6 weeks after each brace fitting)		-	-
Compliance	-	-	SEN	-	-
Treatment switching	-	-	MN	-	-
Patient-reported measures					
SRS-22, CHU9D, RCADS 25, PROMIS sleep ×2	-	IP/E	IP/E	IP/E	IP/E
Brace preference	-	IP/E	-	-	-
BAPQ	-	IP/E	IP/E*	-	-
BSSQ, CSD OPUS (while in brace only)	-	-	IP/E	-	-
Educational information (summer of year 11)	-	-	E†	E†	E†
Other treatments prescribed to treat scoliosis	-	IP/E	IP/E	IP/E	IP/E
Parent questionnaires					
Ethnicity	-	E	-	-	-
Resource Use Questionnaire	-	E	E	E	E
Patient Cost Questionnaire	-	E	-	-	-
School attendance	-	E	E	-	-
Harms					
Complications and SAEs	-	-	IP/E	E	E

*BAPQ to be completed at baseline/randomization and at first six-month follow-up only.
†Collected summer of year 11, age 16, independent of where the patient is in the study.
BAPQ, Brace Adherence Prediction Questionnaire; BSSQ, Bad Sobernheim Stress Questionnaire; CHU9D, Child Health Utility instrument; CSD OPUS, Client Satisfaction with Devices module of the Orthotics and Prosthetics User's Survey; CT, central team; E, electronic, online via an email link sent to the patient (may be chased by mail or telephone); IP, in person; MN, medical notes or BSR form; PROMIS, Patient-Reported Outcome Measurement Information System; RAC, radiological adjudication committee; RCADS 25, Revised Children's Anxiety and Depression Scale-25; SAEs, serious adverse events; SEN, sensor, implanted into brace; SRS-22, Scoliosis Research Society Questionnaire 22-Item.

Data on adverse events and serious adverse events will be tabulated and presented by treatment arm. This will include the number and percentage of participants reported as having any adverse event.

Health economic analysis. Different bracing options are likely to result in different costs, whether due to intervention costs, other related healthcare costs, or subsequent surgery costs, and may result in different health-related quality of life. We will estimate the relative cost-effectiveness (CE) of NTB compared to FTB and will present results for two key outcome measures: cost per quality-adjusted life years (QALYs) gained, and cost per surgery avoided.

The primary CE analyses will take an NHS and personal social services perspective in accordance with NICE,[26] and the primary cost per QALY analysis will take a lifetime perspective, with proportions of patients who do and do not progress to surgery estimated based upon curve size. A secondary analysis will present cost per QALY results restricted to the trial follow-up period. Intervention costs will be based upon information collected to include the type of brace and the resource use associated with fitting it. Wider resource use will include any other healthcare costs incurred that are related to the brace or scoliosis. Health-related quality of life will be estimated using the

Child Health Utility instrument (CHU9D) questionnaire,[19] allowing preference-based utility scores to be estimated, and QALYs to be derived.

Qualitative study. During the early phase of trial recruitment, a qualitative study will explore patients' and parents' views of the trial recruitment processes and perspectives on the two treatments. This will identify ways to enhance trial recruitment and families' experiences of research for the remainder of the trial, i.e. through improvements to communication or information materials. Qualitative findings will also be important to inform ways to support patients in wearing braces as prescribed, and to assist with interpreting the quantitative data at the end of the trial. Few previous studies have explored patients' experiences of bracing for AIS despite the challenges they face, and no such research has been conducted with UK patients.[27–29]

Site staff will request consent from families to forward their contact details to the qualitative study researcher. This includes families who take part in the trial, but also those who decline. In-depth semi-structured interviews will be conducted with a purposive sample of 20 to 25 patient-parent dyads at three to nine months into bracing treatment. Sampling will aim for data saturation and be reviewed in light of developing analyses. Topic guides were developed collaboratively with a Patient and Public Involvement (PPI) group.

Monitoring

Data monitoring. Conduct of the study is overseen by three committees: an independent Trial Steering Committee (TSC) to oversee overall trial conduct, an independent Data Monitoring and Ethics Committee (DMEC) to monitor safety of trial participants, and a Trial Management Group (TMG), responsible for the day-to-day running of the trial. Each committee has a charter or terms of reference, which outlines the roles and responsibilities in full.

Some scoliosis curves will progress despite brace treatment; this will be monitored by the DMEC. In-brace correction will also be monitored by treatment arm by the DMEC, with any concerns escalated to the Trial Steering Committee (TSC) for potential further training.

Remote monitoring will regularly review trial data, missing data, and data queries for timely resolution. Annual remote site monitoring calls, with triggered on-site visits, will take place should any of the pre-agreed triggers be met.

Adverse events. An adverse event (AE) for this study is defined as any untoward medical occurrence in a study participant which is considered to be possibly related to brace treatment, or complications arising from spinal surgery. Scoliosis surgery is an expected outcome for this patient population; this will not be recorded elsewhere in the case report forms. Expected AEs are listed as follows: severe pain from the brace, requiring brace adjustment or re-design; and stage 1 medical device-related pressure ulcer (injury) (skin erythema which is non-blanching with pressure).

AEs/serious AEs (SAEs) meeting the following definitions will be reported in line with standard SAE reporting procedures: Stage 2a, superficial abrasions; Stage 2b, partial-thickness skin loss; Stage 3, full-thickness skin loss (dermis and epidermis) (SAE); and Stage 4, full-thickness tissue loss (SAE).

Ethics and dissemination. The study will be conducted in accordance with Good Clinical Practice,[30] and to protect the human rights and dignity of the patient as reflected in the Declaration of Helsinki.[31]

The BASIS RCT was given a favourable ethical opinion from the North of Scotland Research Ethics Committee 1 (21/NS/0038) on 8 April 2021. Health Research Authority (HRA) approval was granted on the same day. Local confirmation of capacity and capability will be obtained from all participant trust Research & Development departments prior to each site opening for recruitment.

Protocol amendments. The current version of the study protocol is v3.2, 3 August 2023. Any further amendments to the protocol will be agreed with the funder, sponsor, TSC, DMEC, and TMG as required, and submitted to the HRA and REC for approval.

Patient confidentiality. Access to source data and documentation to conduct trial monitoring, audits, and regulatory inspection is sought from participants' parents during informed consent. Participants, once they reach the age of 16, will consent to provide access to their medical notes.

Both the researchers and clinical care teams will ensure patients' anonymity is maintained, and that unauthorized parties do not have access to their identifiable data. Patients will each be assigned a unique study ID number which will be used in correspondence, but identifiable details are available on the study database as this is a clinical registry.

At the end of the study, all data will be securely archived by participating sites and Sheffield Clinical Trials Research Unit (CTRU) for a minimum of 15 years.

Patient and public involvement and engagement

A Patient and Public Involvement & Engagement (PPIE) group was formed at the study design stage. The group contributed to study design and assisted with the production of patient-facing study materials such as information sheets, consent forms, patient questionnaires, topic guides for the qualitative study, and the study website. This ensured that ease of understanding, readability, and the format were appropriate. Any significant amendments to patient-facing documents will be discussed with these representatives prior to implementation.

Two PPIE representatives are part of the TMG and attend meetings regularly, and a third is an independent member of the TSC. PPIE meetings are held separately with these representatives to ensure their

ideas are shared, and any questions they have can be answered outside of the larger meetings. PPIE representatives will be consulted for all patient-focused dissemination activities, and on an ad hoc basis throughout the study when their input would be particularly valuable. PPIE will also be consulted in relation to eventual implementation and knowledge mobilization work relating to the study.

Dissemination

A publication and dissemination plan was developed in conjunction with study co-applicants, to document criteria for authorship, planned outputs, and an agreed process for producing and submitting all outputs directly relating to the BASIS study.

Results from the qualitative work will be published as soon as they are available, and may help to inform the ongoing dissemination strategy.

Trial results will be disseminated in peer-reviewed scientific journals and at clinical and academic conferences. A plain-language summary of the results will be made available to all study participants who consent to receive trial information, and on the study website at the end of the trial. The main results will be published on the NIHR HTA journal website.

Take home message

- In patients with adolescent idiopathic scoliosis, there is strong evidence for the effectiveness of full-time bracing, but it has an adverse effect on quality of life.
- We need to know whether night-time bracing is non-inferior to full-time bracing, and whether quality of life is improved compared to full-time bracing.
- This study addresses four of the top 12 priorities set in the James Lind Alliance partnership for scoliosis.

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