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BASIS Study - Comparing night-time versus full-time bracing in adolescent scoliosis (sideways curvature of the spine)

Submission date
14/04/2021

Recruitment status
Recruiting

Registration date
19/04/2021

Overall study status
Ongoing

Last Edited
18/10/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Scoliosis is a condition affecting children where the spine twists and curves to the side, often developing between the ages of 10 and 15. Doctors try to prevent the curve becoming too large, as this causes distress due to appearance, and problems into adulthood (back pain and problems with the heart/lungs). A brace may be worn in order to stop the curve worsening, but rarely improving it. The most common type of brace, “full-time brace”, is recommended to be worn for at least 20 hours a day, and evidence suggests it can work. The alternative is a “night-time brace”, which is only worn in bed at night, and aims to push the curve to make it straighter overnight, though the evidence for its benefit less clear. Night-time braces can interfere less with patients’ usual activities. This study will compare night-time braces with the full-time brace and will find out patients’ experiences of the two.

Who can participate?
Children (10 - 15 years old) with scoliosis who have not previously received bracing.

What does the study involve?
Participants will be randomly allocated to receive either a full-time brace, or a night-time only brace. Patients will be followed up with regular appointments and back x-rays, and will remain in brace until they have finished growing or need to have surgery. After bracing is stopped, patients will have further clinic visits at 1 and 2 years. Interviews will also take place with some participating families to understand their experiences of bracing.
Two patient groups and an online survey of Scoliosis Association UK (SAUK) members have reviewed the study and feel this is a relevant and important question. The groups have inputted into the design of the study, and we will continue to work closely with the group during the study.

What are the possible benefits and risks of participating?
Patients who do not take part in the trial would be treated using a full-time brace which can be uncomfortable to wear and cause skin irritation, especially in the first few months. This may also occur with the night-time brace used in this study, but this has no additional risks. Young people

who take part in this study, and their families, will be contributing to important research that will inform treatment choices for patients in the future. Young people who take part will also be under close follow-up, which is normal for those taking part in research. The night-time brace is currently only available through this study, but only to those allocated to this at the start.

Where is the study run from?
University of Sheffield (UK)

When is the study starting and how long is it expected to run for?
January 2021 to October 2032

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Katie Ridsdale, k.ridsdale@sheffield.ac.uk

Study website
https://basisstudy.org/

Contact information

Type(s)
Public

Contact name
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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
291133

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 48820, IRAS 291133

Study information

Scientific Title
Bracing Adolescent Idiopathic ScoliosIS (BASIS) Study – night-time versus full-time bracing in adolescent idiopathic scoliosis

Acronym
BASIS

Study objectives
Night-time only bracing is non-inferior to full-time bracing in preventing curve progression to 50 degrees or more in children with Adolescent Idiopathic Scoliosis (AIS), before skeletal maturity

Added 14/05/2024:
BASIS 2 embedded study:
Aim: To determine if, amongst children at skeletal maturity who were successfully treated with a brace for AIS, 6 months of additional bracing significantly reduces curve progression and is acceptable to patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/04/2021, North of Scotland Research Ethics Committee (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, UK; +44 (0)1224558458; gram.nosres@nhs.net), ref: 21/NS/0038

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
https://basisstudy.org/resources/

Health condition(s) or problem(s) studied
Sideways curvature of the spine (scoliosis)

Interventions
Current intervention as of 30/05/2023:
The trial is being conducted in 22 large NHS trusts. Patients with AIS will be identified within the clinic setting - these will either be new patients or patients that are already seeking treatment for AIS, but haven't met the threshold for bracing. Eligibility will be confirmed by the site researcher and information given. Consent/assent will be taken online via a telephone call with the research nurse. Consenting participants will then be randomised to receive either FTB or NTB.

Data will be collected in three phases:
Phase 1: Pre-skeletal maturity
Whilst in brace, patients will be seen routinely every 6 months for clinical monitoring. Routinely collected spinal radiographs will be taken at each visit in order to measure the Cobb angle (primary outcome). Such radiographs will be sent through the Image Exchange Portal after each routine visit and clinical data entered onto the BSR by research staff. Patients will be emailed a link to the questionnaires in the BSR before the 6 month visit. If not completed, they will use a computer or tablet in the clinic to complete the questionnaires. Questionnaire completion will be checked and chased by mail or telephone as required. If the primary outcome is reached (progression to 50 degrees), follow up pre-skeletal maturity will continue via email link to the BSR which will collect PROMs every 6 months. This will include asking patients if they have received surgery, their quality of life and pain.
"Treatment Switching" will not be encouraged but will be recorded including the reason for crossover. Follow-up will continue unchanged.

Phase 2: Post-skeletal maturity
Phase 2 follow-up will commence once skeletal maturity is reached (Risser 4 in girls, Risser 5 in boys). It is important to follow-up patients with AIS after skeletal maturity as some curves will continue to progress. If the patient reaches skeletal maturity with a curve below 50 degrees, follow-up will involve spinal radiographs at 12 and 24 months to assess any curve progression. This is part of routine follow-up as recommended by the Scoliosis Research Society.

Questionnaires will be administered by the BSR at 12 and 24 months after skeletal maturity collected by the email link or in the clinic. Again, data will be checked and chased by email or telephone as required.

If the curve progresses to 50 degrees or more, the patient may or may not have surgical treatment. If they don't have surgical treatment, follow-up with spinal radiographs and questionnaires will be done at 12 and 24 months as above, If the patient has surgery, radiographs and questionnaires will be completed at routine post-operative clinic follow-up at 6-8 weeks, 1 year and 2 years after surgery.

Phase 3: Long-term follow up
If consent is obtained from the patient, follow-up will continue for 10 years after skeletal maturity (i.e. up to 8 years after the end of the trial). This will be funded separately from this current funding award and ethics application.

The project also included a qualitative sub-study, undertaken during the internal pilot phase, to explore patients' and parents' views of the trial recruitment processes and perspectives on the two treatments. This involved in-depth semi-structured interviews with over 20 families at 3-9 months into bracing treatment. This component is now complete, analysis is underway, and we hope that results will be reported soon.

Added 14/05/2024:
BASIS 2:
BASIS 2 will run parallel with BASIS as a 'nested' study with no additional clinic visits. There will be one additional hand/wrist x-ray (to determine skeletal age), one additional questionnaire at baseline, and one additional questionnaire at 6 months after randomisation into BASIS2. The study will be completed concurrently with the BASIS study, with both studies reporting their results 2 years after skeletal maturity.

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Previous intervention:
The trial will be conducted in 19 large NHS trusts (we currently have 23 potential centres from which 19 will be selected to take part). Patients with AIS will be identified within the clinic setting - these will either be new patients or patients that are already seeking treatment for AIS, but haven't met the threshold for bracing. Eligibility will be confirmed by the site researcher and information given. Consent/assent will be taken online via a telephone call with the research nurse. Consenting participants will then be randomised to receive either FTB or NTB.

Data will be collected in three phases:
Phase 1: Pre-skeletal maturity
Whilst in brace, patients will be seen routinely every 6 months for clinical monitoring. Routinely collected spinal radiographs will be taken at each visit in order to measure the Cobb angle (primary outcome). Such radiographs will be sent through the Image Exchange Portal after each routine visit and clinical data entered onto the BSR by research staff. Patients will be emailed a link to the questionnaires in the BSR before the 6 month visit. If not completed, they will use a computer or tablet in the clinic to complete the questionnaires. Questionnaire completion will be checked and chased by mail or telephone as required. If the primary outcome is reached (progression to 50 degrees), follow up pre-skeletal maturity will continue via email link to the BSR which will collect PROMs every 6 months. This will include asking patients if they have

received surgery, their quality of life and pain.
“Treatment Switching” will not be encouraged but will be recorded including the reason for crossover. Follow-up will continue unchanged.

Phase 2: Post-skeletal maturity
Phase 2 follow-up will commence once skeletal maturity is reached (Risser 4 in girls, Risser 5 in boys). It is important to follow-up patients with AIS after skeletal maturity as some curves will continue to progress. If the patient reaches skeletal maturity with a curve below 50 degrees, follow-up will involve spinal radiographs at 12 and 24 months to assess any curve progression. This is part of routine follow-up as recommended by the Scoliosis Research Society. Questionnaires will be administered by the BSR at 12 and 24 months after skeletal maturity collected by the email link or in the clinic. Again, data will be checked and chased by email or telephone as required.

If the curve progresses to 50 degrees or more, the patient may or may not have surgical treatment. If they don’t have surgical treatment, follow-up with spinal radiographs and questionnaires will be done at 12 and 24 months as above, If the patient has surgery, radiographs and questionnaires will be completed at routine post-operative clinic follow-up at 6-8 weeks, 1 year and 2 years after surgery.

Phase 3: Long-term follow up
If consent is obtained from the patient, follow-up will continue for 10 years after skeletal maturity (i.e. up to 8 years after the en d of the trial). This will be funded separately from this current funding award and ethics application.

The project also includes a qualitative sub-study, which will be undertaken during the internal pilot to explore patients’ and parents’ views of the trial recruitment processes and perspectives on the two treatments. This aspect will involve in-depth semi-structured interviews with a purposive sample of 20-30 patient-parent dyads at 3-9 months into bracing treatment. Families will be purposively sampled to encompass diversity in key characteristics and a small sub-set of families who decline to take part in BASIS will also be interviewed. Interviews will be audio-recorded, transcribed and analysed using qualitative techniques.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Back brace

Primary outcome measure
1. Curve progression is measured using the Cobb angle (measured from x-ray), every 6 months, before skeletal maturity, and then at 1 and 2 years post skeletal maturity.

Added 14/05/2024:
BASIS 2:
Curve progression from baseline to 2 years after skeletal maturity, in degrees. These will be assessed by the Central Measurement Team.

Secondary outcome measures
1. Quality of life is measured using the Scoliosis Research Society 22 questionnaire, every 6 months until skeletal maturity, and then at 1 and 2 years post skeletal maturity.
2. Health related quality of life is measured using the CHU9D questionnaire, every 6 months until skeletal maturity, and then at 1 and 2 years post skeletal maturity.
3. Psychological effects of bracing is measured using the Bad Sobernheim Stress Questionnaire questionnaire, every 6 months until skeletal maturity, and then at 1 and 2 years post skeletal maturity.
4. Quality of life is measured using the Revised Children's Anxiety and Depression Scale (RCADS 25) questionnaire, every 6 months until skeletal maturity, and then at 1 and 2 years post skeletal maturity.
5. Sleep disturbance is measured using the PROMIS Paediatric Sleep Disturbance Short Form 4a tool, every 6 months until skeletal maturity, and then at 1 and 2 years post skeletal maturity.
6. Sleep-related impairment is measured using the PROMIS Paediatric Sleep Related Impairment Short Form 4a tool, every 6 months until skeletal maturity, and then at 1 and 2 years post skeletal maturity.
7. Patient satisfaction with their brace treatment is measured using the Modified Client Satisfaction with Device module of the Orthotics and Prosthetics Users' Survey (CSD-OPUS) questionnaire, annually.
8. Education information and attainment is measured using a bespoke questionnaire, once, after the patient has completed their GCSEs (or equivalent).
9. Patient cost is measured using a bespoke questionnaire to the parents, every 6 months until skeletal maturity, and then at 1 and 2 years post skeletal maturity.
10. Healthcare resource use is measured using a bespoke questionnaire to the parents, every 6 months until skeletal maturity, and then at 1 and 2 years post skeletal maturity.
11. School attendance is measured using a bespoke questionnaire to the parents, every 6 months until skeletal maturity, and then at 1 and 2 years post skeletal maturity.
12. Curve progression is measured using x-ray (Cobb angle, curve type, curve apex, Risser sign, in-brace Cobb angle, frontal plane balance, apical vertebral rotation, apical vertebral translation), every 6 months until skeletal maturity.
13. In brace correction is measured by Orthotist assessment every 6 months until skeletal maturity.
14. Brace compliance is measured by a wear-time sensor inserted into the brace, and data is collected on a continuous basis, and downloaded when each brace is removed.
15. Complications and serious adverse events are recorded throughout the study.

Added 14/05/2024:
BASIS 2:
Patient bracing experience, and any preferences for full-time or night-time bracing, measured using the Skeletal Maturity Bracing Questionnaire at baseline

Overall study start date
01/01/2021

Completion date
31/10/2032

Eligibility

Key inclusion criteria

1. Children (10–15 years old inclusive) with a diagnosis of AIS; (some patients recruited at age 15 may be 19 years old by the time they have completed their 2 years after skeletal maturity follow-up)
2. Risser 0, 1 or 2
3. Curve size (Cobb angle) between 20 and 40 degrees inclusive at baseline
4. Curve apex at or below T7
5. Participants and their parent/legal guardian must have a good understanding of the English language to ensure they understand what is required as part of the trial

Added 14/05/2024:
BASIS 2:
1. Participants enrolled on the BASIS study
2. RAC confirms skeletal maturity (Risser 4 in girls, Risser 5 in boys) with a Cobb angle less than 50o

Participant type(s)
Patient

Age group
Child

Lower age limit
10 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
Planned Sample Size: 780; UK Sample Size: 780; BASIS 2 Sample Size: 228

Key exclusion criteria
1. Secondary causes of scoliosis (i.e. neurological abnormalities and abnormal imaging)
2. Previous bracing or spinal surgery
3. Child or parent is unable to adhere to trial procedures or complete follow-up

Date of first enrolment
10/11/2021

Date of final enrolment
31/10/2026

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
Sheffield Children's Hospital
Sheffield Children's NHS Foundation Trust
Western Bank
Sheffield
United Kingdom
S10 2TH

Study participating centre
Alder Hey Children’s Hospital
East Prescot Road
Liverpool
United Kingdom
L14 5AB

Study participating centre
The Royal Orthopaedic Hospital
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Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Bristol Royal Hospital for Sick Children
St. Michaels Hill
Bristol
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BS2 8BJ

Study participating centre
Royal Stoke University Hospital
Newcastle Road
Stoke-on-trent
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ST4 6QG

Study participating centre
Musgrave Park Hospital
Stockmans Ln
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United Kingdom
BT9 7JB

Study participating centre
Taunton Hospital
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
The James Cook University Hospital
Marton Road

Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Royal Manchester Childrens Hospital
Hospital Road
Pendlebury
Swinton
Manchester
United Kingdom
M27 4HA

Study participating centre
Royal National Orthopaedic Hospital
Brockley Hill
Stanmore
United Kingdom
HA7 4LP

Study participating centre
Southampton
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Leeds General Infimary
Great George Street
Leeds
United Kingdom
LS1 3EX

Study participating centre
Royal Hospital for Children and Young People
50 Little France Crescent
Edinburgh

Lothian
United Kingdom
EH16 4TJ

Study participating centre
Great Ormond Street Hospital
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London
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Sponsor information

Organisation
Sheffield Children's NHS Foundation Trust

Sponsor details
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S10 2TH
+44 (0)114 2717000
paul.dimitri@nhs.net

Sponsor type
Hospital/treatment centre

Website
https://www.sheffieldchildrens.nhs.uk/

ROR
https://ror.org/02md8hv62

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR131081

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/01/2032

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.4	08/08/2022	30/05/2023	No	Yes
Participant information sheet	version 1.2	08/02/2022	30/05/2023	No	Yes
Participant information sheet	version 2.2	08/02/2022	30/05/2023	No	Yes
HRA research summary			28/06/2023	No	No
Participant information sheet	BASIS 2 (aged 16 years and over) version 1.0	25/03/2024	14/05/2024	No	Yes
Participant information sheet	BASIS 2 (parent) version 1.0	25/03/2024	14/05/2024	No	Yes
	version 4.0		14/05		

Protocol file	25/01/2024	/2024	No	No