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ResearchActivityInSchoolsEvaluatingDental health (RAISED In Yorkshire)

Submission date 04/10/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 08/08/2024	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 01/04/2026	**Condition category** Oral Health	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Yorkshire has the second-worst UK prevalence of tooth decay; affecting almost 1/3rd of children before they reach school. Tooth decay is concentrated to high-risk groups within areas of deprivation, presenting a considerable health, economic and social burden. Whilst tooth decay is preventable, reaching those most at-risk remains challenging. With approaching 50% of young children starting secondary school with decayed teeth there is an enormous health need to address this.

RAISED in Yorkshire (RiY) offers a novel peer-to-peer delivery approach to address oral health inequality. RiY is a feasibility randomised controlled trial (RCT) of a complex intervention. RiY trains 16-18-year-old-students from underserved communities as 'RiY-Student Research Fellows' (RiY-SRFs) to deliver oral health interventions to 11-13-years old students. RiYrelies onsharedcultural backgrounds and relatability to reach students that may be missed by typical healthcare professional-led interventions.

Study aim:

To establish RiY with its peer-peer delivery model within the secondary school setting supported by Foundation Dentists as an effective and sustainable approach to improve oral health awareness and efficacy (toothbrushing) in adolescents from underserved at-risk communities.

Who can participate?

The study will involve pupils from Key Stage 3 (age 11-13 years old, focused primarily on Year 7). The study will be undertaken in up to six schools/colleges in Yorkshire, these schools serve a diverse population with high dental need. RiY-SRFs will be invited to take part in dental checks, YUK oral bugs project, and focus groups to evaluate any added benefit from their participation in the study.

What does the study involve?

The intervention consists of:

• One interactive, classroom based oral health session comprising of 3 interactive workshops, delivered by trained RiY-SRFs
• Oral hygiene with demonstration of brushing technique
• Being sugar smart
• Understanding the importance of going to the dentist

Further reinforcement teaching activities, including for example the YUK-Oral Bugs sub-study and further tooth brushing skills reinforcements (such as tooth brushing clubs).

The control group will receive current standard of care with regards to oral health education and a delayed RiY lesson post final data collection period. This is necessary to assess any added value the intervention provides.

The primary outcomes of interest are change in knowledge, skills and behaviour.
Each consented adolescent has the following measures recorded at 2 intervals across the project:
• Change in toothbrushing skills (measured by Plaque index & Gingival Index at baseline & post-intervention)
• Change in knowledge/attitude/behaviour (measured by Adapted WHO Oral Health questionnaireat baseline & post-intervention)
• Tooth decay (measured by DMFT (Diseased, Missing, and Filled Teeth) recorded only at baseline)

This information will be collected by suitably trained, qualified and calibrated foundation dentists, supervised by the research team from the University of Leeds.

What are the possible benefits and risks of participating?
The study will provide oral health education in a fun interactive way. The aim is to improve knowledge and skills around dental health, which potentially has a long-term health benefit. RiY provides Sixth form students with an opportunity to be involved in research, gain knowledge of higher education, and exposure to mentorship, while enabling the staff and students from the School of Dentistry to collaborate with representatives from under-served communities with high dental need.
The main risk in the study is embarrassment about poor oral health knowledge and skills. Care will be taken to ensure individuals are not targeted when answering questions and undertaking tasks. Any concerns about 'at risk' pupils based on the brief dental check will be highlighted to schoolteachers who are familiar with the pupils and family and who have clear safeguarding protocols in place.

Whilst unlikely, participants may experience non-serious expected adverse events such as minor discomfort, or may become upset due to minor bleeding during the dental check. Safety monitoring will be undertaken throughout the study. Participants with immunosuppression and bleeding conditions such as haemophilia are excluded from participation due to the small risk. All dentists performing dental checks are GDC registered dentists who are trained to resolve and manage any such issue and care will be taken to review any concerns with the study team when they arise.
A full risk assessment will be submitted to the School of Dentistry, University of Leeds and shared on request with participating schools.

Where is the study run from?
The study is run from the Dental Translation and Clinical Research Unit (DenTCRU) based at the School of Dentistry at the University of Leeds (UK)

When is the study starting and how long is it expected to run for?
September 2019 to September 2028

Who is funding the study?
The University of Leeds is the sponsor of the study. Funding has been obtained from:
• An Oral and Dental Research Trust Robin Davies Award.
• Health Education England /NHS England
• West Yorkshire Integrated Care Board
• Enhanced Research Culture Grant from the University of Leeds
• NIHR CRN (Clinical Research Network)- Yorkshire & the Humber

Who is the main contact?
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Integrated Research Application System (IRAS)
323514

Central Portfolio Management System (CPMS)
54745

Study information

Scientific Title
RAISED In Yorkshire: ResearchActivityInSchoolsEvaluatingDental health

Acronym
RAISED In Yorkshire

Study objectives
1. Is it operationally feasible to deliver Raised in Yorkshire (RiY) to multiple secondary school within the school timetable supported by Foundation Dentists?
2. Is RiY an effective way to provide Oral Health Education for Key Stage 3 adolescent/teenagers when delivered collaboratively by trained peers from Year 12 & 13 (16-18 years old)?
3. Is it feasible to collect oral samples for YUK Oral Bugs Project from students participating in RiY?
4. Is it feasible for schools to provide pseudo-anonymised data on RiY participants on i) free school meal status (proxy for deprivation) ii) broad classification on education attainment

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/02/2023, School of Dentistry, University of Leeds Research Ethics Committee (DREC) (School of Dentistry, University of Leeds, Worsley Building, Clarendon Way, Leeds, LS2 9NL, United Kingdom; +44 113 3436210; j.k.mcdermott@leeds.ac.uk), ref: 200218/SP/242-A / 200218/SP/242-B

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Paediatric Dentistry

Interventions
The intervention consists of:
• Three interactive, classroom based oral health workshops, delivered by trained RiY-Student Research Fellows (RiY-SRFs) oral health champions.
• Further reinforcement teaching activities, including for example the YUK-Oral Bugs sub project.

The consented Year 7 students will be randomly allocated into 2 arms; intervention and control group. This will roughly be a 2:1 or 3:1 ratio (as it is a feasibility trial, it will be a convenience proportion based pragmatically on the schools' form structure, timetabling and availability of our team).

The intervention group will receive the RiY interactive classroom teaching, from the RiY-SRFs, consisting of an introduction session and three interactive workshops, which provide small group teaching and practical demonstrations to reinforce key oral hygiene messages. The introduction session has been designed for use in this study to ensure the oral health messages are clear and consistent with the research outcomes. Volunteer foundation dentists will train the Year 12 RiY-SRFs to deliver the oral health programme. The workshops content broadly covers the topics:
• Oral hygiene with demonstration of brushing technique
• Being sugar smart
• Understanding the importance of going to the dentist

The control group will receive current standard of care with regards to oral health education and a delayed RiY lesson post final data collection period. This is necessary to assess any added value the intervention provides. All teaching staff will have access to any resources delivered to the intervention group, post final oral health data collection. This ensures all pupils benefit from provision of oral health support.

To facilitate evaluation of the programme and explore added benefits to the RiY-SRFs, they will be invited to provide written optional consent to undergo dental assessments (consent for saliva sampling will be undertaken as part of the YUK-Oral Bugs sub-study). This will allow researchers to evaluate if RiY-SRFs receive oral health benefits as a result of taking part in the programme.

Intervention Type
Other

Primary outcome(s)
Feasibility outcomes:
1. Recruitment rate of participants, withdrawal, and acceptability of randomisation
2. Feasibility of training sixth form students as oral health educators
3. Feasibility of deploying dental foundation trainees
4. Ability to collect dental health data & link to school's data

Saliva Sample collection for YUK Oral Bugs Project
5. Number of participants consenting to saliva sampling
6. Ability to collect samples in schools at baseline and Post intervention

Key secondary outcome(s)
Clinical efficacy:
1. Change in toothbrushing skillsvia Plaque index & Gingival Index (baseline & post-intervention)
2. Knowledge/attitude/behaviour via Adapted WHO Oral Health questionnaire (baseline & post-intervention)
3. DMFT/deft score (recorded only at baseline)

Process evaluation:
4. Questionnaires &interviews with key stakeholders (e.g., RiY-SRFs and teachers) to understand

RiY experience, school logistics
5. Impact of RiY on school, Yr7 students, logistics and feasibility of student participation

Completion date
30/09/2028

Eligibility

Key inclusion criteria
Selection of the schools:
1. Schools based in West Yorkshire. Ideally have an integrated or linked 6th form college. If it doesn't have 6th form college,will rely on partnership with a participating school.
2. Have free school meal eligibility criteria of 13 and above (as a marker of deprivation of students).
3. Ofsted rating of the school showing ideally good,excellent or outstanding. But consideration of school who are improving is a possibility.
4. Willingness of schools to contract for data sharing agreement of basic demographics of pupils FSM and education attainment level (low medium high or other similar classification.

Selection of 6th form peer educators:
1. Year 12 (13) students who are interested in joining the RiY enrichment.
2. Self-select with an interest in RiY or careers on STEM or education.
3. Consent and parental consent to take part in the programme.

Key stage 3 pupils:
1. All year 7 students from participating forms that are medically fit to participate and can assent to participate.
2. Must understand spoken English (or have a support worker available to assist).
3. Must have written parental consent.

Participant type(s)
Learner/student

Healthy volunteers allowed
No

Age group
Child

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Unwilling to consent,participate,severe physical disability,unsafe airways,allergy to any materials being used.

2. Any KS3 pupils who have a medical concern e.g.,nil by mouth,severe physical disability and immunocompromised.
3. School assistant unavailable to support students who do not speak/understand English

Date of first enrolment
07/02/2023

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Batley Girls High School
Windmill Lane
Batley
England
WF17 0LD

Study participating centre
Allerton Grange School
Talbot Avenue, Roundhay
Leeds
England
LS17 6SF

Study participating centre
Roundhay School
Old Park Road
Leeds
England
LS8 1ND

Study participating centre
Ralph Thoresby High School
Holtdale Approach

Leeds
England
LS16 7RX

Study participating centre
Dixons City Academy
Ripley St
Bradford
England
BD5 7RR

Study participating centre
Dixons Sixth Form Academy
Douglas Mills Bowling Old Lane
Bradford
England
BD5 7JR

Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Charity

Funder Name
Oral and Dental Research Trust

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		31/03/2026	01/04/2026	Yes	No
Other files	Guidance on Accessing NHS Dental Care version 1.0		08/08/2024	No	Yes
Other files	RiY Advice on Accessing NHS Dental Care for Parents		08/08/2024	No	Yes
Other files	RiY Combined YUK-Parental Consent form version 1.0		08/08/2024	No	Yes
Other files	RiY Combined YUK-Parental Consent form version 1.0		08/08/2024	No	Yes
Other files	RiY Conference Letter to Parents version 1.0		08/08/2024	No	No
Participant information sheet	RiY-Parental information sheet version 1.0	05/02/2023	08/08/2024	No	Yes
Participant information sheet	RiY-YUK-SRF information sheet version 1.0	12/12/2022	08/08/2024	No	Yes