

A Germ's Journey Soaper Heroes: Interactive educational handwashing interventions for children to increase understanding of health hygiene and reduce infection rates on paediatric hospital wards

Submission date 13/05/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/05/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/10/2024	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Washing your hands is one of the easiest ways to protect yourself and others from illnesses such as food poisoning and flu.

'A Germ's Journey Soaper Heroes' are hand-hygiene resources centred on superhero-type characters. This research project aims to study the effectiveness of this educational intervention in children and young people aged 3-21 years staying on hospital wards.

Who can participate?

All children and young people (aged 3 - 21 years) on the chosen wards (selected by the infection control nurses) will be included in the study, unless recommended otherwise by the lead infection control nurse at each specific NHS Hospital Trust.

Healthcare staff and nurses who have cared for the children who have received the educational intervention will also be included.

What does the study involve?

The educational intervention will involve children receiving a box containing handwashing products and accompanying health-educational resources. The box will contain anti-bacterial hand wipes, anti-bacterial hand gel and soap all manufactured and provided by the project's funders PAL International. Alongside the products, specifically developed educational resources including stickers (as part of a reward-system style sticker-chart), a colourful zine (a small booklet that unfolds into a flat poster) containing information about germs in a poster form.

The researchers will complete observations of NHS healthcare staff and children engaging with 'Germ's Journey' health-education resources and products. The researchers will only observe how the children interact with the staff and resources and the children's handwashing practices. Researchers will not complete any interview/focus groups with the children.

Brief interviews/focus groups/questionnaires with NHS healthcare staff will be conducted regarding their own experiences using the resources with the children on the wards and to evaluate if the resources have supported them in their infection control role and distinguish if there has been a change in children's handwashing practices.

What are the possible benefits and risks of participating?

Benefits: reduction of infection rates in the ward(s) as well as an increased understanding of infection control in children

Risks: The healthcare staff will check if each child has any allergies to the product's ingredients prior to giving them to each child. If a child is allergic to any of the handwashing products, these will not be included in that child's box and care will be taken not to let the child come into contact with the product(s) they are allergic to. Should an allergic reaction occur due to unknown allergies, the standard care protocol would be adhered to and the child will be seen by a medic.

Where is the study run from?

De Montfort University (UK)

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

January 2020 to September 2023

Who is funding the study?

Pal International Limited (UK)

Who is the main contact?

Dr Katie Laird, klaird@dmu.ac.uk

Study website

<http://www.germsjourney.com>

Contact information

Type(s)

Scientific

Contact name

Dr Katie Laird

Contact details

De Montfort University

School of Pharmacy

The Gateway

Leicester

United Kingdom

LE1 9BH

+44 (0)116 207 8106

klaird@dmu.ac.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

273440

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 43704, IRAS 273440

Study information

Scientific Title

A Germ's Journey Soaper Heros: Interactive educational handwashing interventions for children to increase understanding of health hygiene and reduce infection rates on paediatric hospital wards

Study objectives

What effect/impact does an educational intervention using 'A Germ's Journey Soaper Heroes' hand-hygiene resources have on paediatric patients' (children's) handwashing practice and understanding of infection prevention practices, and infection rates on the ward(s)? The proposed research will add to the limited published literature on the need for the use of interactive health hygiene public health messages for young children and how implementing such activities in paediatric hospital wards can reduce infection rates.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 28/02/2020, De Montfort University's Health and Life Sciences Research Ethics Committee (Faculty Research Ethics Committee, Faculty of Health and Life Sciences, De Montfort University, Research and Innovation Office, 3.35 Edith Murphy House, The Gateway, Leicester, LE1 9BH, +44 (0)116 207 8228; hlsfro@dmu.ac.uk), ref: 20/WA/0010

Study design

Non-randomized; Both; Design type: Prevention, Process of Care, Education or Self-Management, Qualitative

Primary study design

Observational

Secondary study design

Longitudinal study

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Prevention of infection

Interventions

Observations

The researchers will observe two 'groups' of paediatric patients:

The observations will be 'Non-Participant Observations', meaning that the researcher will not play any part in what is being observed. Observations will only be taken when healthcare staff are present.

The research team will consist of a team of academics and a PhD student from De Montfort University (DMU) and NHS Staff. The researchers will complete observations of NHS healthcare staff with children engaging with "Germ's Journey" health-education resources and products. The researchers will only observe how the children interact with the staff and resources and the children's handwashing practices. Researchers will not complete any interview/focus groups with the children. The researchers themselves will not approach or ask the children questions. Should the children start up a conversation (regarding the study) with the researchers whilst they are observing, notes may be taken (e.g – specific terminology used/feedback of the resources). Children will remain completely anonymous.

PAEDIATRIC PATIENTS ON SHORT-STAY WARD (ARM 1)

Observations will be undertaken, looking specifically at children on the short-stay ward's engagement with the resources and their handwashing practice with:

A) Normal procedures in place.

B) Handwashing products (e.g – anti-bacterial wipes/hand-gel) given to children with food, with no Germ's Journey resources/ intervention.

C) Handwashing products given to children alongside the Germ's Journey education resources/ intervention

A combination of observation tally-sheets of behaviour and field notes will be used when observing. Each scenario (A,B &C) will take place with all patients on the short-stay ward sequentially over a 3-4 days.

The Research Team aim to conduct the study in Jan/Feb 2020 during the flu and cold seasons in order to collect data on the impact of interventions aimed at reducing infection rates. Each intervention (a-c) will be conducted over a period of 3-4 days.

PAEDIATRIC PATIENTS ON LONG-STAY WARD (ARM 2):

When observing the patients on the Long-Stay Wards, handwashing champions (healthcare staff) employed by the NHS Hospital Trust will be asked to encourage the use of the Germ's Journey Soaper Heroes resources and products on wards over a 6 month period. Observations of usage will be conducted at approximately 2, 4 and 6 months using the same method of observation (tally-sheets and field notes).

Interviews/focus groups (Arm 2)

Brief interviews/focus groups (approx. 10 minutes) will be conducted with healthcare staff, where it is not possible to interview, a short questionnaire (containing the same questions as the

interview/focus groups) will be used. The interviews/focus groups/questionnaire will focus specifically on:

A) The implementation of the resources

B) how the resources were used

C) The healthcare staffs' own observations of children's interactions with the Germ's Journey Soaper Heroes resources

Questions will be a combination of closed (Yes/No, multiple choice) and open-ended questions, to allow for qualitative and quantitative data analysis.

Infection rate data (Arm 2)

The Germ's Journey Soaper Heroes handwashing products and educational resources will be left with the short-stay ward managers to distribute to the patients for 2-3 months following the initial start of the study, due to the short stays of patients on these wards, more patients will be admitted and discharged at a quicker rate to that of the long-stay ward. On the long-stay ward it is likely that the same children will be situated on the wards during the follow-up periods (2, 4 and 6 months post initial site visit).

Observing the two wards will enable the researchers to compare the effectiveness of the educational intervention between the long-stay and short-stay patients, and to evaluate whether having the resources imbedded within the patients day-to-day routine and re-enforced in the wards over a longer period of time on the long-stay ward has more of an impact.

Infection rate data from both the Short-Stay and Long-Stay wards in the NHS Hospital Trusts will be compared between the period when the Germ's Journey Soaper Heroes intervention is in place to that of previous corresponding time period (six months) when there was no handwashing intervention.

Data Analysis

Quantitative Data:

Infection rate data will be analysed using the statistical programme SPSS to ascertain if differences in infection rates are statistically different between the same 3-6 month period in the year prior to the Soaper Hero intervention being introduced and the corresponding months when the intervention had been implemented. Two-way t-tests assuming unequal variances will be conducted to identify significant differences ($p < 0.05$). A Mann Whitney U test will be used where assumptions of a normal distribution are not met according to the Anderson-Darling test. Frequency of Healthcare Staff's responses to interviews/questionnaires will also be analysed using SPSS, using Chi-Squared or Fisher's Exact Test to ascertain a statistical difference in responses.

Qualitative data:

Qualitative data from the observations and interviews/focus groups/open-ended questions in the questionnaire will be analysed using thematic analysis (a method for identifying, analyzing and reporting patterns within data), using Braun and Clarke's (2006) framework. This framework involves reading the data, generating initial codes, systematically identifying key findings, naming codes and reporting these findings.

Before commencement of the study, a Local Information Pack will be emailed to all local hospital collaborators.

Intervention Type

Behavioural

Primary outcome measure

Infection rates on paediatric wards pre- and post-intervention using Infection rate data accessed via Meditech by an experienced NHS operative approximately 12 months after the commencement of the first observations on the wards

Secondary outcome measures

1. Children's understanding of germ transmission and children's handwashing behaviour will not be formally measured, observations of children's interaction and engagement of the handwashing resources and products will be conducted on the NHS Trust Sites wards by the researchers in October 2020 and then 2, 4, 6 and 12 months after the commencement of the first observations on the wards, each over a period of 3-4 days. Healthcare Staff at the hospitals will be asked to distribute the resources and share any observations they have in the periods where researchers are not observing
2. Healthcare staff's experience of using the educational intervention measured using interviews /focus groups or if more convenient or if for whatever reason an interview/focus group cannot be conducted, a short questionnaire containing the same questions will be given to the healthcare staff to complete in their own time. Interviews/focus groups/questionnaires will be carried out at both NHS Trust Sites approximately 4, 6 and 12 months after the commencement of the first observations on the wards

Overall study start date

27/01/2020

Completion date

01/09/2023

Eligibility

Key inclusion criteria

1. Children and young people (aged 3-21 years) on the chosen wards (selected by the infection control nurses), unless recommended otherwise by the lead infection control nurse at each specific NHS Hospital Trust
2. Healthcare staff and nurses who have cared for the patients who have received the educational intervention

Participant type(s)

Patient, Health professional

Age group

Mixed

Lower age limit

3 Years

Sex

Both

Target number of participants

Planned Sample Size: 70; UK Sample Size: 70

Total final enrolment

57

Key exclusion criteria

1. Child or young person too ill to participate

Date of first enrolment

01/11/2021

Date of final enrolment

30/11/2021

Locations**Countries of recruitment**

United Kingdom

Study participating centre**Three UK hospitals**

Requested to remain anonymous to maintain blinding

United Kingdom

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Sponsor information**Organisation**

De Montfort University

Sponsor details

De Montfort University, School of Allied Health Sciences

Leicester

Leicester

England

United Kingdom

LE1 9BH

+44 (0)116 257 7658

douglas.gray@dmu.ac.uk

Sponsor type

University/education

Website

<http://www.dmu.ac.uk/home.aspx>

ROR

Funder(s)

Funder type

Industry

Funder Name

Pal International Limited

Results and Publications

Publication and dissemination plan

The findings of the study are intended to be published in peer reviewed journal and/or PhD thesis. Findings may also be disseminated at an education or scientific conference and on the research project's website (<http://www.germsjourney.com>) and social media platforms. The Sponsor (De Montfort University) owns the data resulting from this study and the Funder, PAL International will be acknowledged in any publications. At the end of the research, a full study report will be given to the NHS Trust Sites and any publication will be forwarded to the lead contact at each. Any healthcare staff involved in the study will have the right to request a final copy of the study report. The patient forum who were involved with the initial discussions of the study will also be informed of the study's findings.

Intention to publish date

27/06/2024

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication.

Data will be analysed by the research team at De Montfort University. The researchers will not be taking or storing personal data but all other data associated with the research will be kept on De Montfort University (DMU) computers (password-protected) for 5 years in accordance to DMU policy. Data will be stored in a password-protected data repository programme (Figshare) at De Montfort University (DMU). This data will only be accessible to the research team on the outlined research study. The findings of the study are intended to be published in peer-reviewed journal and/or PhD thesis. Findings may also be disseminated at an education or scientific conference and on the research project's website (<http://www.germsjourney.com>) and social media platforms. The Sponsor (De Montfort University) owns the data resulting from this study and the Funder, PAL International will be acknowledged in any publications. At the end of the research, a full study report will be given to the NHS Trust Sites and any publication will be forwarded to the lead contact at each. Any healthcare staff involved in the study will have the right to request a final copy of the study report. The patient forum who were involved with the initial discussions of the study will also be informed of the study's findings.

IPD sharing plan summary

Stored in non-publicly available repository, Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Results article		23/09/2024	03/10/2024	Yes	No
Other files	Results summary		04/10/2024	No	No