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Nottingham**

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# **The MAGIC project: involving children and young people in research to improve the study design and success**

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University of Nottingham





# Outline

- Rationale
- Project background
- Project PPIE
- Examples of YPAG involvement
- Project outcomes
- Summary



FUNDED BY

**NIHR** | National Institute for  
Health and Care Research



# Rationale

- Recent exponential rise in development of medical devices
- Great opportunities for patient benefit and for business
- However, the sector is dominated by adult healthcare
- Development for children often gravitates towards the repurposing of adult's applications, frequently assuming that devices can simply be made smaller
- Essential to involve children and young people in the identification of unmet needs, and in the development of workable, 'real-world' products and solutions that will address their needs



© imagegently.org



Paul Dimitri et al. Pharmaceutics 2021, 13, 2178

**NIHR** | Children and Young People  
MedTech Co-operative

**ePTRI**  
EUROPEAN PAEDIATRIC TRANSLATIONAL RESEARCH INFRASTRUCTURE





# Project background – paediatric constipation

- 14% of children suffer from constipation at some point in their life
- Managing illness in these children is challenging, and the diagnosis often unclear and based mostly on symptom reports
- An objective measure of the whole gut transit time (WGTT) available early in the clinical pathway can help with early selection of therapy



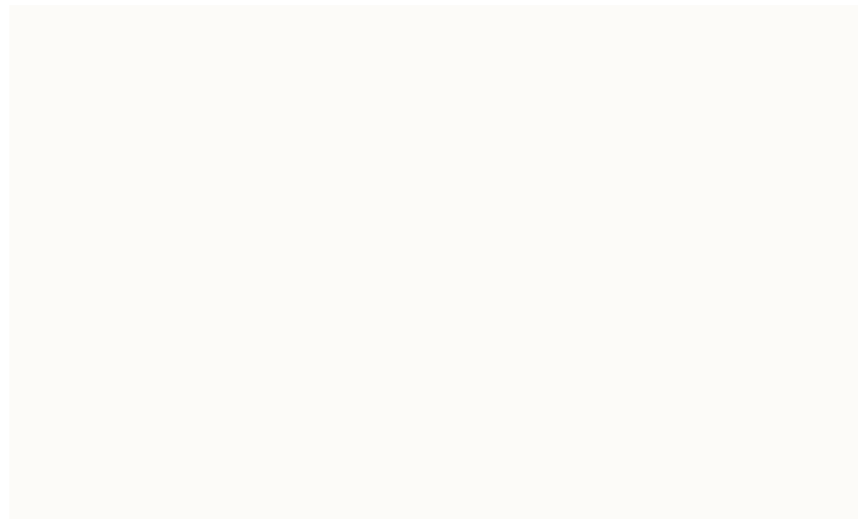
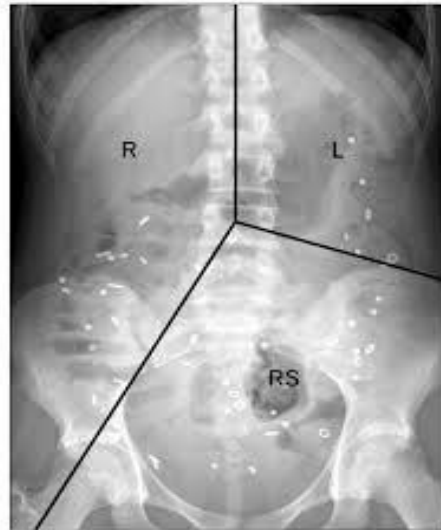


# Project background – the new medical device

- Current X-ray radiopaque marker (ROM) method uses ionizing radiation
- Has poor anatomical definition of colon loops



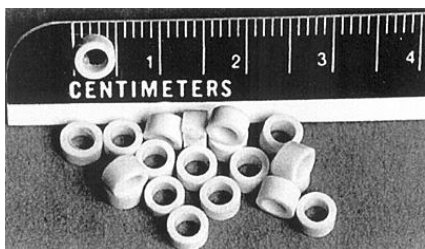
X-ray test



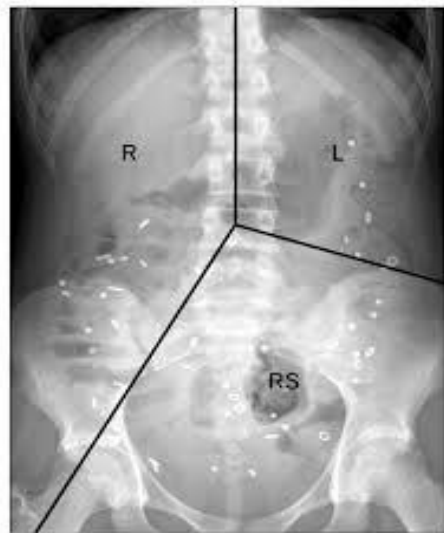


# Project background – the new medical device

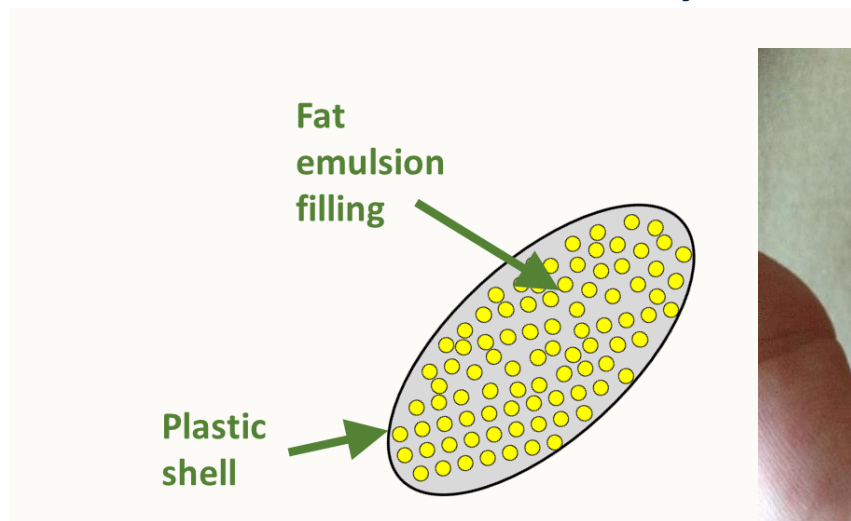
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X-ray test



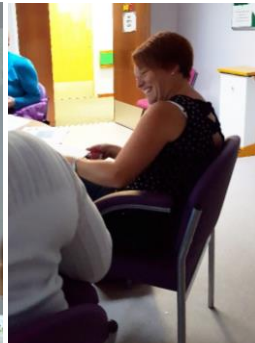
- Our innovation: magnetic resonance imaging (MRI) equivalent of ROMs
- Funded by 2 x NIHR i4i PDAs
- Small (8mm×4mm), inert, plastic mini-capsules, filled with a MRI-visible fluid
- Manufactured by JEB Technologies





# PPIE

- Parent Co-Applicant
- Parents Advisory Group
- Young Persons Advisory Group (YPAG)
- PPIE budgets: 4% - 6% of grant totals

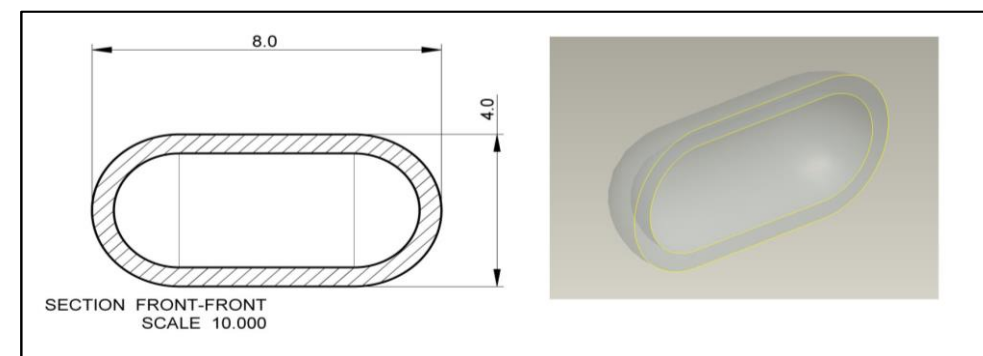
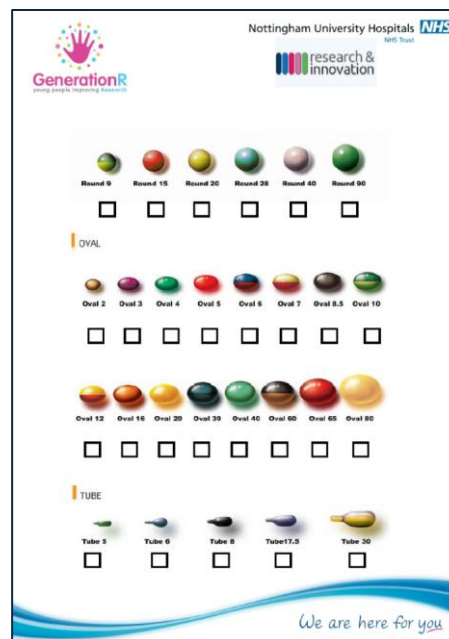






# YPAG involvement – device design

Co-design of the mini-capsules,  
interacting directly with the SMEs





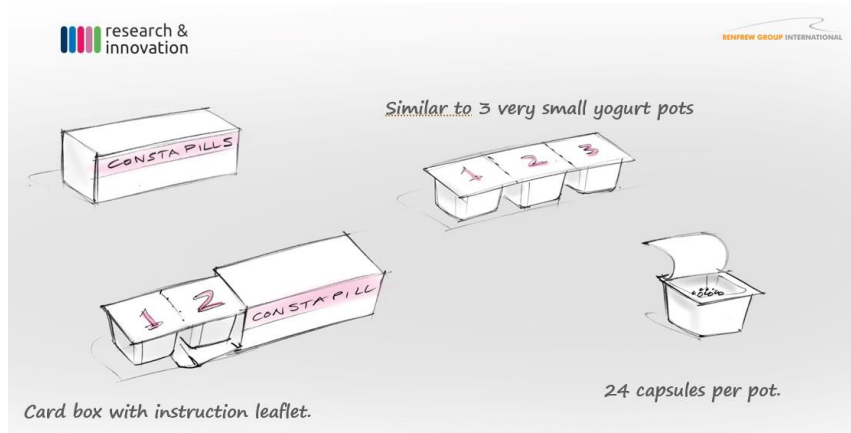


# YPAG involvement – packaging

Co-design of the packaging,  
interacting directly with the SMEs



Mark I



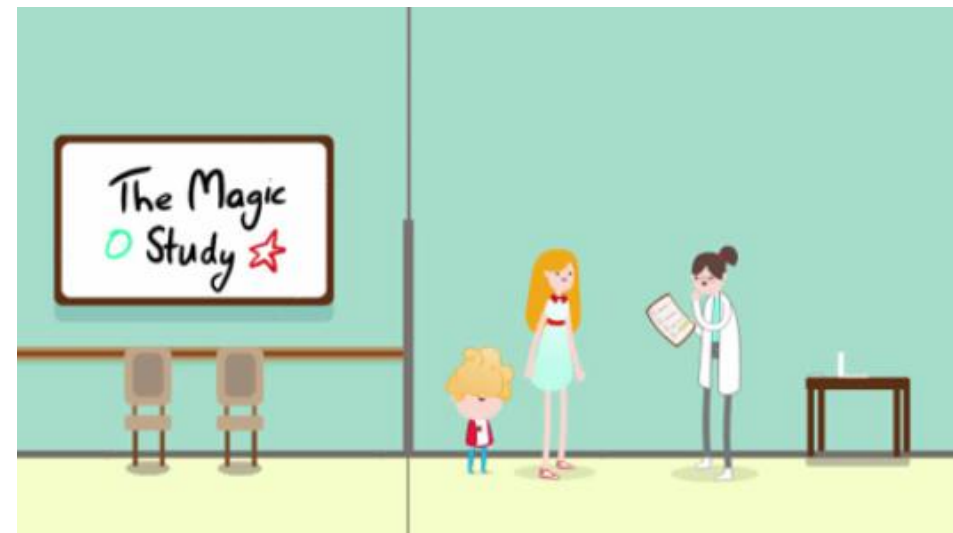
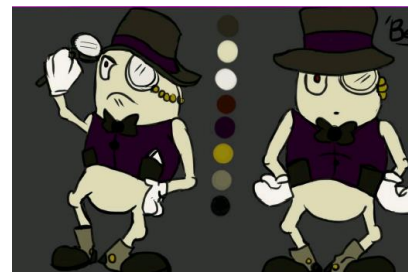
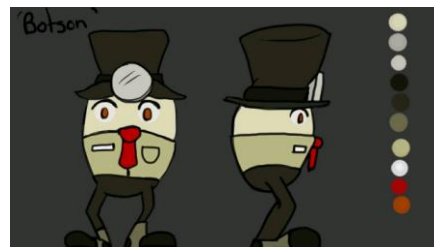
Mark II



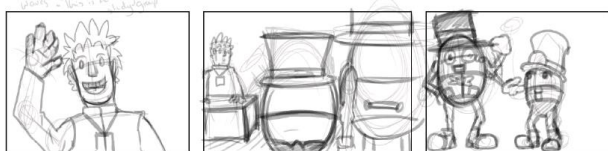


# YPAG involvement – animated info sheets

Co-design and voice of two animated info sheets for the clinical investigation, interacting directly with animation specialists



STORYBOARDS



<https://youtu.be/luvlutiTvr4>  
<https://youtu.be/w5O8lhZqEs8>





# YPAG involvement – presentations and management

Co-present at conferences



Part of project management group

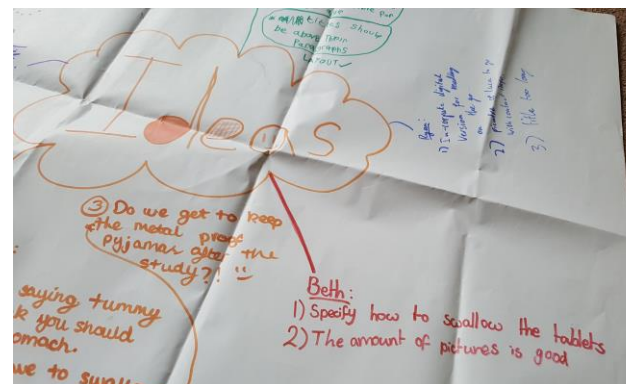




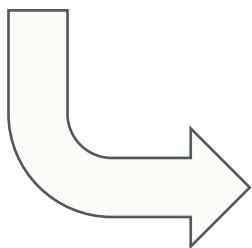


# YPAG involvement – Ethics materials

Co-production of Ethics materials appropriate and understandable for children of different ages



What the Ethics Committee said



**Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity**

The Committee commended the applicants on their engagement with patients and parents/carers whilst designing the study and participant information. They commented this was clearly reflected in the quality of the submission.



# YPAG involvement – co-authors on publications

ORIGINAL ARTICLE: GASTROENTEROLOGY

OPEN

## Feasibility Study of a New Magnetic Resonance Imaging Mini-capsule Device to Measure Whole Gut Transit Time in Paediatric Constipation

\*<sup>†</sup>Hayfa Sharif, \*Nichola Abrehart, \*<sup>‡</sup>Caroline L. Hoad, \*<sup>‡</sup>Kathryn Murray, \*<sup>§</sup>Alan C. Perkins, \*<sup>‡</sup>Murray Smith, \*<sup>‡</sup>Penny A. Gowland, \*Robin C. Spiller, \*Roy Harris, \*<sup>†</sup>Sian Kirkham, \*<sup>†</sup>Sabarinathan Loganathan, \*<sup>†</sup>Michalis Papadopoulos, \*<sup>†</sup>Kate Frost, The Young Persons Advisory Group (YPAG), \*<sup>†</sup>David Devadason, and \*<sup>‡</sup>Luca Marciani

### ABSTRACT

**Objective:** In England, 27,500 children are referred annually to hospital with constipation. An objective measure of whole gut transit time (WGTT) could aid management. The current standard WGTT assessment, the x-ray radiopaque marker (ROM) test, gives poor definition of colonic anatomy and the radiation dose required is undesirable in children. Our objective was to develop an alternative magnetic resonance imaging (MRI) WGTT measure to the x-ray ROM test and to demonstrate its initial feasibility in paediatric constipation.

**Methods:** With the Nottingham Young Person's Advisory Group we developed a small (8 × 4 mm), inert polypropylene capsule shell filled with MRI-visible fat emulsion. The capsule can be imaged using MRI fat and water in-phase and out-of-phase imaging. Sixteen patients with constipation and 19 healthy participants aged 7 to 18 years old were recruited. Following a common ROM protocol, the participants swallowed 24 mini-capsules each day for 3 days and were imaged on days 4 and 7 using MRI. The number of successful studies (feasibility) and WGTT were assessed. Participants' EuroQol Visual Analogue Scale were also collected and compared between the day before the taking the first set of mini-capsules to the day after the last MRI study day.

**Results:** The mini-capsules were imaged successfully in the colon of all participants. The WGTT was 78 ± 35 hours (mean ± standard deviation) for patients, and 36 ± 16 hours,  $P < 0.0001$  for healthy controls. Carrying out the procedures did not change the EuroQol Visual Analogue Scale scores before and after the procedures.

**Conclusions:** Magnetic Resonance Imaging in Paediatric Constipation was a first-in-child feasibility study of a new medical device to measure WGTT in paediatric constipation using MRI. The study showed that the new method is feasible and is well tolerated.

### What Is Known

- Current methods for assessing whole gut transit time include the traditional abdominal x-ray and radiopaque markers.
- X-ray radiopaque marker methods expose children and young people ionizing radiation in the range 0.03 to 0.11 mSv.
- >X-ray radiopaque markers produce 2-dimensional radiographs in which the bowel and location of the radiopaque markers may be difficult to distinguish.

### What Is New

- We developed a new, magnetic resonance imaging visible mini-capsule, specifically aimed at children and young adults.
- This first-in-child feasibility study showed that whole gut transit time can be measured in paediatric constipation using the new mini-capsule device in conjunction with magnetic resonance imaging.

**F**unctional constipation in childhood is common, with estimated prevalence of 14% (1–5). The diagnosis is based on symptom and is defined according to the Rome IV diagnostic criteria (6–8)

Abrehart et al. *Research Involvement and Engagement* (2021) 7:2  
<https://doi.org/10.1186/s40900-020-00243-0>

Research Involvement  
and Engagement

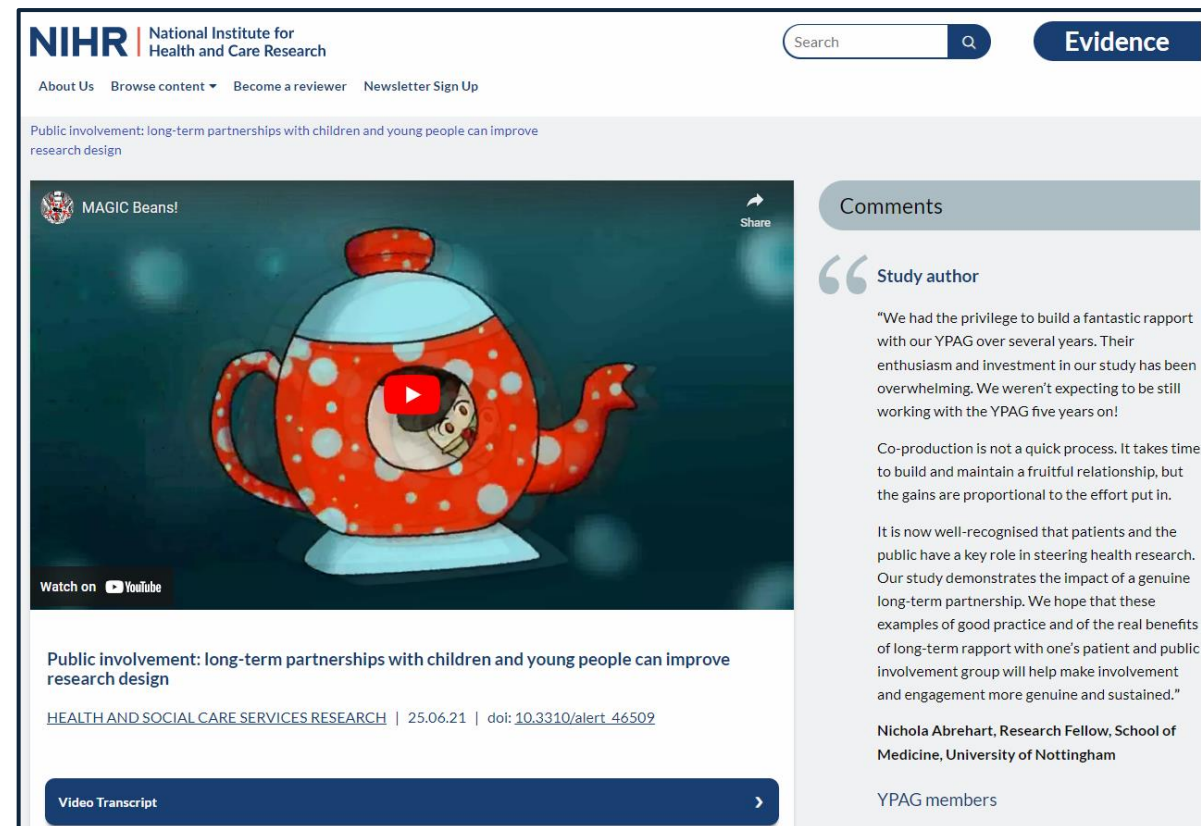
## COMMENTARY

Open Access

“A little (PPI) MAGIC can take you a long way” : involving children and young people in research from inception of a novel medical device to multi-centre clinical trial *Roald Dahl, James and the Giant Peach* (1961)

Nichola Abrehart<sup>1\*</sup>, Kate Frost<sup>1</sup>, the Young Persons Advisory Group<sup>2</sup>, Roy Harris<sup>1</sup>, Andrew Wragg<sup>2</sup>, Derek Stewart<sup>2</sup>, Hayfa Sharif<sup>1</sup>, Rachel Matthews<sup>3</sup> and Luca Marciani<sup>1</sup>









# Project outcomes to date

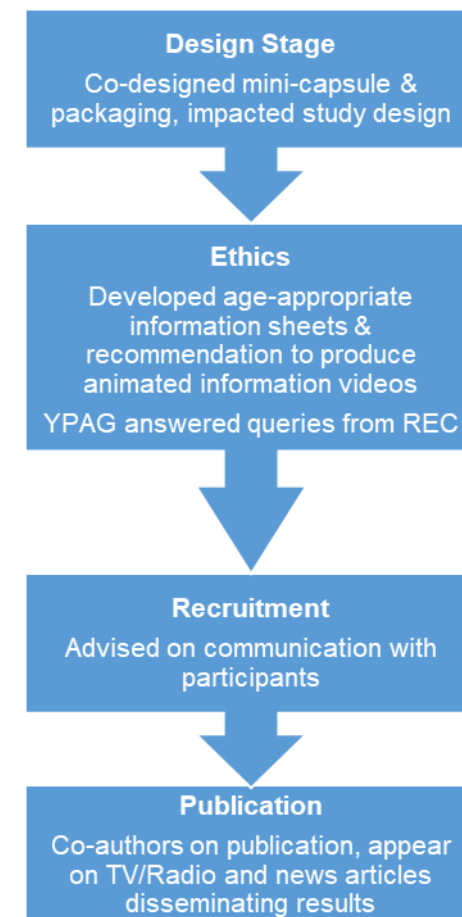
- Partnership with the YPAG
- Partnership with JEB Technologies
- £1.86 million raised so far
- 7 patents granted + 1 pending
- Registered international trademark “TransiCap”
- 3 publications + 1 under review
- First-in-child study
- Manufacturing line
- New grant being written to take TransiCap to UKCA/CE marking and to market !





# Summary

- Co-production is not a quick process
- Planning, resourcing, staffing, executing PPI meetings and building a relationship with the members is time intensive but extremely rewarding
- Involvement of the YPAG over the last 8 years, led to the development of a mutually beneficial partnership, enabling genuine knowledge exchange between researchers, SMEs and the children and young people
- This influenced positively the design, plans and actions of the MAGIC project to date, and continues into the next phase



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Thank you !

