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

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Supplemental Digital Content 1: CONSORT checklist

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Not applicable
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3-4
	2b	Specific objectives or hypotheses	4, 6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5-6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Not applicable
Participants	4a	Eligibility criteria for participants	4-5
	4b	Settings and locations where the data were collected	4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5-6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	11
Sample size	7a	How sample size was determined	Not applicable
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not applicable
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	Not applicable
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Not applicable
Allocation concealment	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Not applicable

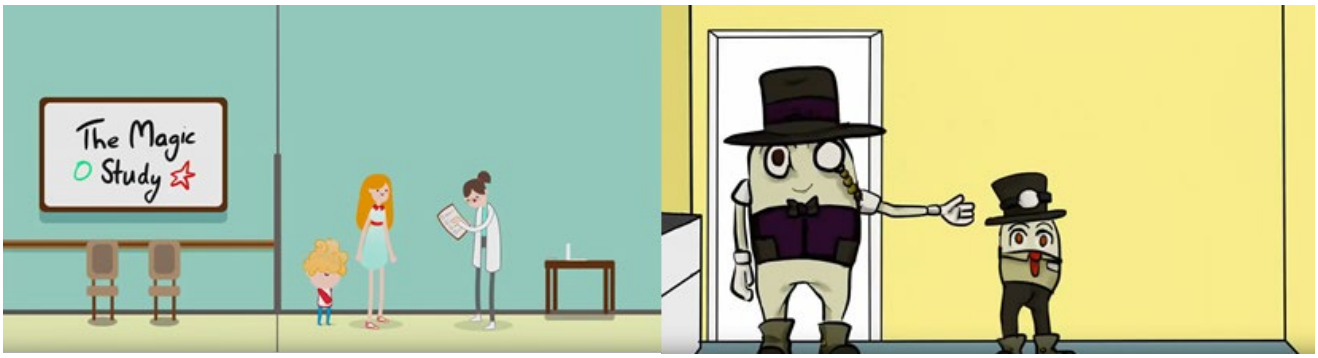
mechanism			
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Not applicable
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Not applicable
	11b	If relevant, description of the similarity of interventions	Not applicable
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8-9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8-9
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	4
	14b	Why the trial ended or was stopped	Not applicable
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	9, Suppl Table 2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	9-11
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	9-11
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Not applicable
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	13-14
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	14-15
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11-13
Other information			
Registration	23	Registration number and name of trial registry	5
Protocol	24	Where the full trial protocol can be accessed, if available	Not applicable
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Title page

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Supplemental Digital Content 2: Supplemental Text

Patient and Public Involvement and Engagement

The patient and public involvement and engagement (PPI/E) in this project was recurrent and meaningful since inception. We co-designed and co-produced the Transicap™ mini-capsules and the packaging, with the Young Person Advisory Group (YPAG) working in person with the designers at Renfrew Group International (Abbey Meadows, Leicester, UK) and the technology consultants from the NIHR from the Enteric Health Technology Cooperative. Together with the YPAG members we designed the MAGIC project website www.gastrointestinalmri.org.uk, we scripted, produced and narrated two novel, animated pediatric video info sheets, now Ethics approved and on YouTube https://youtu.be/luvIutiTvr4 and https://youtu.be/w5O8lhZqEs8.



We wrote age-appropriate Ethics information sheets (praised by the Ethics Committee) and presented together at the podium of the Nottingham Pediatric Research Showcase 2018 (winning 2nd best oral presentation) and at the UK Clinical Research Facilities conference 2019.

We continue working with the YPAG and some of their comments on the progress of the co-production can be seen on this video edited from a round-table discussion about the YPAG's participation in the MAGIC programme https://www.youtube.com/watch?v=tPRt75xdq2k.

Supplemental Digital Content 3: Table 1

SUPPLEMENTAL TABLE 1. MRI sequence parameters

MRI sequence	3D T1 weighted TFE [*]	
Image orientation	Axial	Coronal
Field of View	350 mm (RL) × 280 mm (AP)	348 mm (RL) × 250 mm (HF)
Image stacks [†]	5 [‡]	6 [§]
Slices per stack	33	27
Length of breath hold per stack	12.3 s	13.5 s
SENSE acceleration factor	2	2
Signal averaging	1	1
Flip angle	20°	20°
Repetition time TR	10 ms	10 ms
Echo times TE_1 / TE_2	1.32ms / 2.2 ms	1.32ms / 2.2 ms
Reconstruction matrix	400 × 400	400 × 400
Acquired image resolution	1.8 mm × 1.8 mm × 4.4 mm	1.8 mm × 1.8 mm × 4.4 mm
Reconstructed image resolution	0.88 mm × 0.88 mm × 2.2 mm	0.87 mm × 0.87 mm × 2.2 mm

[*] mDIXON sequence on Philips MRI scanner used

[†] The image stacks (packages) were acquired with no gaps between them, reconstructed independently and then put back together as a full section.

[‡] The scanner table moved between each stack

[§] The scanner table moved between a 'top' and a 'bottom' sections and then 3 stacks were acquired at each of these two table positions.

Supplemental Digital Content 4: Table 2

SUPPLEMENTAL TABLE 2. Individual participants' characteristics

Participant number	Patient or healthy control	Age	Gender	Weight (kg)	Height (m)	BMI (kg/m^2)
1	Healthy control	16	Female	63	1.65	23.0
2	Healthy control	17	Female	65	1.63	24.5
3	Patient	8	Male	60	1.30	35.5
4	Healthy control	11	Male	48	1.60	18.7
5	Healthy control	14	Male	52	1.60	20.3
6	Healthy control	16	Female	63	1.70	21.8
7	Patient	11	Male	99	1.67	35.5
8	Healthy control	17	Male	72	1.79	22.5
9	Healthy control	17	Female	70	1.70	24.2
10	Healthy control	15	Female	58	1.59	22.8
11	Patient	10	Female	41	1.05	37.1
12	Healthy control	18	Male	85	1.69	29.8
13	Healthy control	18	Male	91	1.75	29.7
14	Healthy control	17	Male	70	1.73	23.4
15	Healthy control	18	Male	106	1.67	38.0
16	Healthy control	16	Female	59	1.71	20.2
17	Patient	13	Female	60	1.64	22.3
18	Patient	7	Male	25	1.28	15.5
19	Healthy control	14	Female	55	1.60	21.4
20	Patient	8	Female	48	1.30	28.4
21	Healthy control	17	Female	57	1.52	24.7
22	Healthy control	17	Male	80	1.85	23.4
23	Healthy control	15	Female	97	1.79	30.3
24	Healthy control	18	Female	57	1.63	21.5
25	Patient	10	Male	34	1.20	23.6
26	Patient	16	Female	68	1.55	28.3
27	Patient	10	Female	22	1.28	13.2
28	Patient	12	Male	34	1.40	17.3
29	Patient	9	Female	35	1.20	24.3
30	Patient	18	Female	52	1.25	33.3
31	Patient	13	Male	60	1.54	25.3
32	Patient	13	Male	42	1.54	17.7
33	Patient	14	Female	63	1.64	23.4
34	Patient	7	Female	23	1.20	15.9
35	Healthy control	10	Female	42	1.45	20.0

Supplemental Digital Content 5 – Suppl Figure 1. Young participants' EQ-VAS scores before and after undergoing the mini-capsules ingestion and MRI scan procedures. The values shown are mean±standard deviation. Wilcoxon's $P = 0.54$ the patients and $P = 0.55$ for the healthy controls comparing before and after the study procedures respectively.