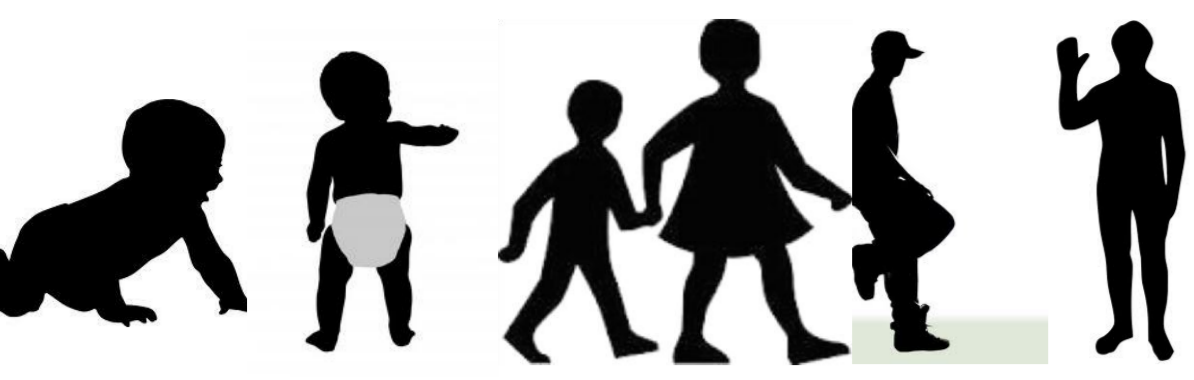


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Background: There are very few reports on the extent and value of engaging children, young people and their families in the development of paediatric clinical research.

Aims:

- To compare the views research aware and research naïve populations of children and young people (CYP) to the views of research aware and research naïve parents.
- To highlight the most appropriate tools to use to facilitate interactions with CYP and parents.
- To determine whether the proposed methodology within the randomised controlled trial aspect of the vitamin D study, with particular reference to the formulation aspects was acceptable to patients and their parents with a view to adapting the methodology to incorporate concerns raised by these groups.

Introduction: Patient and public involvement in clinical trials has been defined as “experimenting with” as opposed to “experimenting on” patients.

Poor design of a clinical trial can result in low recruitment to the study or high drop out from the study which can lead to poor quality data or even abandoning a trial. User involvement at the outset can assist in tackling possible issues early on by listening to the views of potential participants to design-out potential hurdles in the methodology. Therefore high quality research depends on listening to the voices of children and young people, as well as their families and carers, taking account of their experiences, priorities and perspectives.

Involving CYP and families in clinical research is seen as more difficult compared to adults due to perceived ethical concerns. Access to the relevant groups can be complex and there is limited knowledge on which groups provide the most relevant information, particularly whether this is parents or CYP and their existing knowledge of research. This study explores similarities or differences in information on a clinical study design based on the research experience and participant relationship (CYP vs parent).

Study design

A clinical study comparing vitamin D (oily solution) dosed daily for 8 weeks (0.3-0.5mL) vs a single large dose (7.5-12.5mL).

The study also required 2 additional blood samples

Figure 1. Dose volumes required in each arm of the study

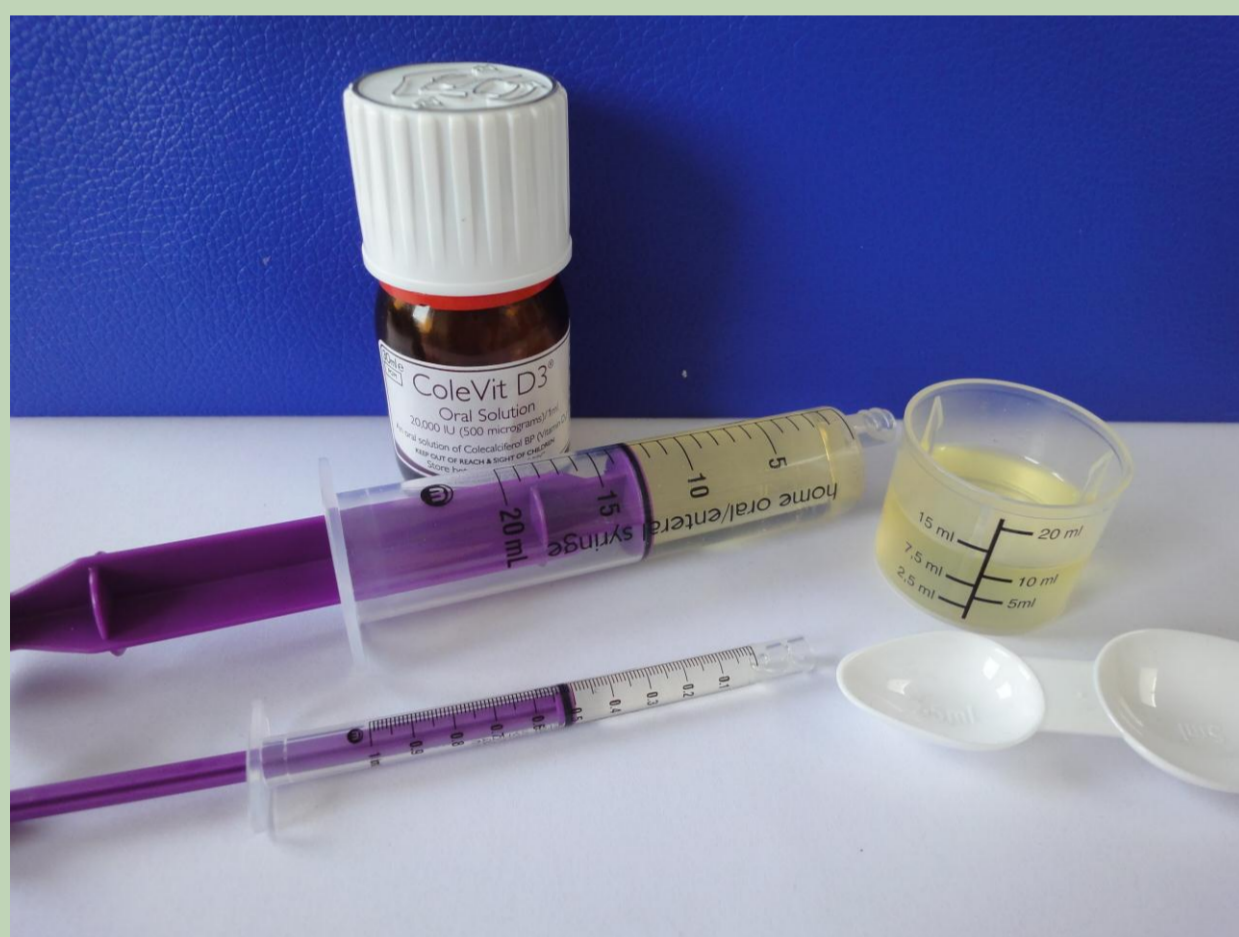
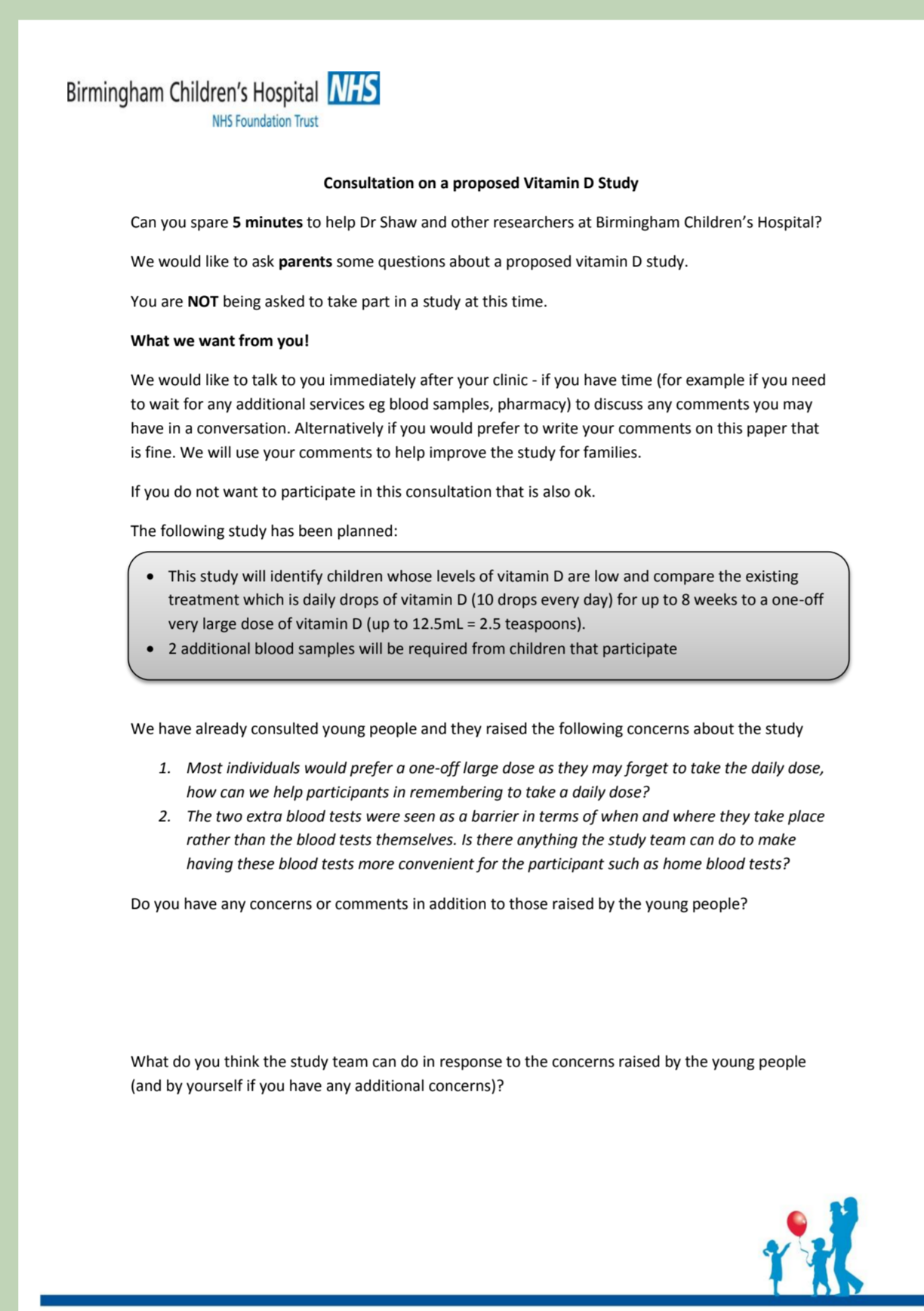


Figure 2. Study information sheet shared with parents



Methods: Populations

Four populations were targeted to understand differences both between CYP and parents as well as research awareness within these populations.

Table 1. Populations and tools involved in this study

	Research aware	Research naïve
CYP	NIHR funded Young Person's advisory group based at Birmingham Children's Hospital Age range 11- 18 years N=10 Focus group methodology used. Facilitated by experts in PPI with CYP	School children visiting a community outreach event (Rare Diseases Day) Age range 12- 16 years N=30 Focus group methodology used (3 sessions; n=10 in each session). Facilitated by experts in PPI with CYP
Parents	The CRN:Children has parents as consumer representatives within each of their clinical study groups N=2 Study information sheet was shared with the consumer representatives for the endocrine CSG for comment	Families attending routine outpatient appointments at the endocrine clinic at Birmingham Children's Hospital N= 8 Study information sheet was shared with structured questions

Methods: Tools

Focus groups were used with the CYP populations, the structure of the questions can be seen in Table 2. Issues identified within the focus groups were used to prepare an information sheet (Figure 2) that was used as the basis of structured interviews with research naïve parents or as the only communication tool with research aware parents.

Results and Discussion: CYP

The two most significant issues raised in both focus groups were; (i) forgetting to take daily medicine and (ii) logistics surrounding the daily blood tests.

The research aware group had further discussions on strategies to help in taking medicine daily and provided some suggestions as below:

Set an alarm on your phone to remind you to take it

Some older people still won't remember even over 18s

The YP should have responsibility from about age 10 to remember to take it

I think you just get into a routine so you would remember to take it

Weekly rewards would also help to stick to the routine

A poster or sticker chart would help young people to keep taking the medicine. There should be a sticker for each day and perhaps the chart should be a pathway or calendar

Get the study team to send a reminder text each day

The second issue identified was the logistics surrounding the additional blood tests. The research team were surprised that the tests themselves were not identified as a barrier. Both groups also provided suggestions to reduce the barrier of these test which related to ensuring that these tests were performed at a time and location convenient for the patient and their family.

Results and Discussion: Parents

The opinions of 8 research naïve families on the two major issues (i) forgetting to take a daily medicine and (ii) convenience of additional blood tests were collected. The opinions are detailed in Table 3.

Opinions of participant families on issues identified by young persons' focus groups associated with the proposed study design.

1. Forgetting to take medicine

- 5/8 families agreed that a sticker chart would be useful
- Text reminders were generally thought to be useful although 2/8 families stated they would NOT like a text reminder. One teenager stated that a visual phone reminder but not a text would be useful

2. Convenience of blood tests

- 7/8 families agreed that a site other than the hospital would be a better site for the blood tests.

Expert parents views

Highlight that measures will be taken to minimise pain (butterfly, Emla® cream)

Spacing and timing of blood tests should be explained to the participants

The size of the single dose is large can this be mixed with food or drink to help the child take this?

Nutella, honey, squirty cream, smoothie, yogurt, milkshake were suggested as good mixers

Can a drink be provided by the study team or a voucher to purchase something known to be suitable?

Conclusions and Further Work

- This study involved both research aware and research naïve young people and their families.
- The same issues were raised by all groups highlighting that research aware individuals with experience of commenting on proposals are representative of the general population and that CYP and parents identify the same issues.
- The research aware groups in addition to identifying issues also provided potential solutions which adds value to the interaction for the research team.

The research team changed their proposal in response to the comments made and added costs to support development and distribution of a sticker chart and a text reminder service to remind those in the daily arm as well as costs for the additional blood tests to be taken at sites other than the main hospital centre.

Access to patient groups was simple as the CRN:Children facilitate engagement with CYP and parents therefore it was a matter of a brief discussion prior to the study and then the time involved in writing/presenting to the group. Overall the time involved was minimal for maximum rewards that will ensure that the study can be delivered more efficiently.