

PARTICIPANT INFORMATION SHEET

You have been invited to take part in a research study. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish to. Do not hesitate to ask us about anything you are not clear about, or if you would like more information, and then decide whether you wish to take part or not. Thank you for reading this.

Title of Project: Investigating the nature of medication related challenges faced by patients that are on Home Enteral Nutrition (HEN), and the action they take to resolve any problems.

Name of Investigators: Saleema Khan, Dr N Ward – Project supervisor

What is the study about?

The number of patients receiving home enteral feeding has increased considerably in recent years. It is now estimated that more than twice as many patients receive enteral nutrition in the community than in hospital.

Enteral feeding tubes are frequently used for medication administration in patients who cannot swallow safely. Several issues must be considered with simultaneous administration of oral medications and enteral formulations, because incorrect administration methods could result in a number of complications.

The aim of this project is to further explore the nature of these complications, and in particular, the patient or their carer's experience of them, and also investigate whether or not any methods exist to minimise or overcome these problems, and the patient or their carer's awareness of these methods.

What does the study involve?

It will involve questionnaires to be filled out by members of the support group PINNT (or their carers), that are on Home Enteral Nutrition. The questionnaires are to be filled out on a secure website, and consist of 13 short questions. The results to the questionnaire will be collated and used in the study.

Why have I been chosen?

Potential volunteers have been chosen by sending of an email by the organisation PINNT to all the members that are on Home Enteral Nutrition like yourself. Taking part in this study is optional. There will be many other research volunteers that will be given the opportunity to take part and data collected by all respondents will remain anonymous.

Do I have to take part?

No, taking part is entirely voluntary. It is up to you to decide whether or not to take part in the research. If you do decide to take part you will be given this information sheet to keep.

I am interested in taking part, what do I do next?

If you are interested in taking part, simply fill out the questionnaire by following the link provided as detailed.

What if I agree to take part and then change my mind?

You can withdraw from the study at any time, without giving a reason.

What are the possible disadvantages and risks of taking part?

There are no risks involved in taking part. The questionnaire will simply take 10-15 minutes of your time.

What are the possible benefits of taking part?

Taking part in this study will potentially give a greater insight into the experiences of patients on HEN. The study will hopefully lead to further studies and may influence the provision of information to HEN patients.

What if something goes wrong? / Who can I complain to?

If you have a complaint regarding anything to do with this study, you can initially approach the lead investigator. If this achieves no satisfactory outcome, you should then contact the Administrator for the Faculty Research Ethics Committee, Research & Commercial Office, Faculty of Health & Life Sciences, 1.25 Edith Murphy House, De Montfort University, The Gateway, Leicester, LE1 9BH or hlsfro@dmu.ac.uk

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept on a password protected database and is strictly confidential. You will be given an ID code which will be used instead of your name. Any identifiable information you may give will be removed and anonymised.

What will happen to the results of the research study?

The results of the research study will be used in a report which may be published or presented. Results will also be made available to PINNT.

Who is organising and funding the research?

The study is part of an MPharm course at De Montfort University.

Who has reviewed the study?

This study has been reviewed and approved by De Montfort University, Faculty of Health and Life Sciences Research Ethics Committee.

Contact for Further Information

For further information or any queries, please contact:

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Thank you for volunteering to take part in this study.