

# A digital platform to optimise participant recruitment and retention in nutrition clinical trials

## Increasing data validity deriving from nutrition clinical trials

Dr Zoe Tolkien, Innovation Centre, University of Bath, Broad Quay, Bath, BA1, UK

Contact: Dr Zoe Tolkien, +44 (0)7944 661991 [zoe.tolkien@cantab.net](mailto:zoe.tolkien@cantab.net)



### Description of the initiative

#### Background / context

The WHO has declared lifestyle disease a global epidemic. The role of diet and nutrition as determinants are well established. Investment in research programmes furthers understanding of the relationship between diet and nutritional disease such as malnutrition, of which clinical trials are an important part.

#### Rationale for the initiative

Clinical trials often fail or require costly extensions because they under-recruit or lose participants during the trial. Furthermore, nutrition trials are particularly challenging, due to the burdensome nature of keeping a food record. Digital platforms have somewhat improved the landscape for dietary assessment but further work is needed to encourage recruitment and retention of participants.

#### Objectives and scope

The initiative is to develop and test a digital tool for nutrition clinical trials which optimises recruitment and retention. The tool will be developed with input from key stakeholders and will be tested as part of a comparative pilot study with NHS patients.

### Planned activities & deliverables

#### Outline the steps to be taken

- 1) Develop a working prototype of the digital tool with input from NHS patient groups, dietitians and clinical investigators.
- 2) Test the prototype in a comparative pilot study with NHS patients. The digital tool will be compared to usual NHS clinical practice. Study outcomes will include i) difference in participant recruitment rates, ii) difference in participant retention rates, iii) difference in handling of adverse events, iv) participant preferences between the two methods.
- 3) Analyse outcomes of the pilot study and improve the tool's design where appropriate.

#### What are the concrete deliverables of the project?

- 1) Technical development of the tool.
- 2) Development of an electronically delivered programme for enhancing recruitment and retention.
- 3) Initial user feedback from NHS patients.
- 4) A small clinical pilot study with NHS patients.
- 5) Study findings, i.e. success appraisal of the recruitment programme.

#### What achievements are possible in the next 12 and 24 months?

TASK NAME	0 - 6 months						7 - 12 months						13 - 18 months						19 - 24 months					
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Develop recruitment programme	█	█	█																					
Develop tool	█	█	█	█	█	█	█	█	█	█	█													
Initial user feedback												█	█											
Improvements to the tool												█	█											
Develop study												█	█											
Implement study																								
Recruitment and data collection																								
Data analysis & report writing																								

### Resources & enablers

#### Describe personnel, financial needs and how the grant will be spent

Dr Tolkien is the project lead with a PhD in Nutrition from the University of Cambridge and experience in conducting clinical trials in collaboration with the NHS. The majority of the grant will be spent on technical development, €28,000. There are no costs associated with developing the recruitment programme, gaining user feedback from NHS patients, developing the pilot study, or analysing the data and producing reports. The remaining €2,000 will be used for administrative costs associated with implementing the pilot study in various NHS sites.

#### What factors will make it successful?

- 1) The developers of the tool have already been selected through a competitive procurement process to ensure that project costs fall within budget and that development work can begin quickly.
- 2) The tool will link with an existing dietary assessment platform (myfood24.org) developed and validated by Leeds University, UK. Linking with myfood24 will provide the tool with a pre-validated dietary assessment system and also increases the cost effectiveness of the project.
- 3) NHS patients will be involved throughout the project so that the tool is tailored to them and their requirements.
- 4) NHS patient groups have already been identified and provided consent to give user feedback.
- 5) The project is supported by the University of Bath Innovation Centre.

### Results/outcomes & expected impact

- **How will the findings be implemented?** The prototype and pilot data generated from this grant will be used to apply for a bigger grant in order to validate the tool in a national, multi-site clinical trial in collaboration with the NHS and an academic partner. Once validated, the aim will be to integrate the tool with usual NHS clinical trial and audit practices.
- **How will this project advance patient care / contribute to optimal nutritional care?** Optimal care relies on strong evidence base, which in turn relies on valid data from high quality clinical trials. This project will demonstrate whether a digital tool can increase the data validity and success of clinical trials in nutrition by optimising participant recruitment and retention. Without reliable data it is not possible to make decisions about the best nutritional care for patients.
- **What makes the project innovative?** The delivery of a programme to enhance participant recruitment and retention to nutrition clinical trials with a view to optimising data validity is entirely novel.
- **Will the project be likely to influence national nutrition policy?** The project has great potential to influence national policy. Effective national policy relies upon sound evidence base, which is generated first and foremost by research efforts. Clinical studies are a vital component of these research efforts upon which national nutrition policy is based.
- **Is the project transferable to other settings / countries?** Yes. The project is a web based digital platform which facilitates transference to any country and area, as it can be used by anyone with an intermittent internet connection, i.e. the internet connection does not need to be continual. The project is a data collection tool so that it may be employed in any nutritional research setting with unlimited scope. The programme for increasing participant recruitment and retention is transferable to other methods of data collection besides digital, including paper-based, telephone, and in-person.