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Oxford Trauma and Emergency Care

Electronic recruitment and consent in a multi-centre randomised clinical trial in an orthopaedic trauma setting

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Introduction

Within a trauma or emergency setting, when limited time is available for the identification of eligible patients and the consent process, an in-clinic setting for recruitment is often favoured.

To date few trials, where prospective patient consent needs to be obtained in a more acute situation, have attempted to recruit without the patient and researcher sharing a location.

The Covid pandemic led to the introduction of alternative approaches to trial procedures. The option of **recruiting patients to a clinical study without face-to-face contact** was introduced into the FAME trial. In addition to potentially reducing infection risk it also could lead to reduced travel and save clinic and patient time.

Aims

To **enhance recruitment** with an **entirely remote** recruitment function.

Methods

- **Bespoke "virtual consent" function**: research staff screened patients and consented them remotely.
- Participant entered baseline data in a home setting, guided by research staff. Neither patient nor researcher need be present in the hospital.
- **Seamless link** to REDCap, FAME's clinical database and RRAMP randomisation system.
- Researcher and patient required a phone, and internet browser access.
- **Training** by central trials unit staff via a simple flowchart, and site training through remote meetings.

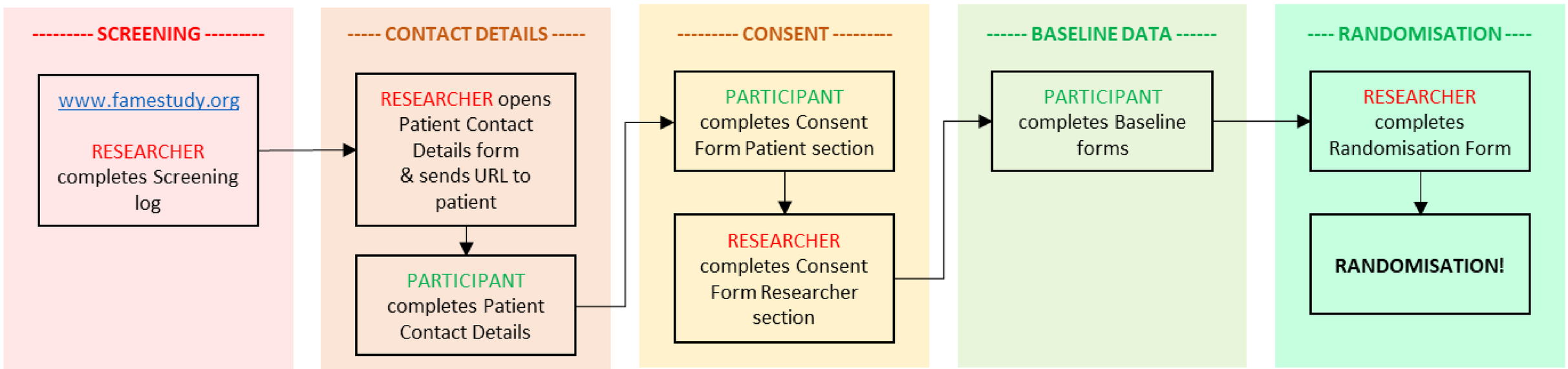

Figure: Virtual consent flowchart

Results

Since virtual consent was introduced to the FAME trial, **34 participants have been randomised using virtual consent** (5% of 657), across 10 of the 24 recruiting sites.

Discussion

Feedback from sites and repeated site use of the function indicate that the virtual consent function is popular.

Self-isolating researchers can work; patients can be randomised at home following virtual fracture clinics.

While research resources were and continue to be under pressure, **patients have been randomised who would otherwise have been missed**.

We recommend that an entirely remote recruitment function is considered as standard for other trials.

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This study is funded by the NIHR (NIHR127273). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

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See also Dr Duncan Appelbe's oral presentation "The development of guidance for the use of eConsent by UKCRC Registered Clinical Trials Units", in session PS.1C - Challenges to Improving Accrual on **Tuesday 4th October**.

ICTMC 2022