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A novel patient-focused approach to home sample collection improves rate of return and sample quality and enables research to continue during the COVID19 pandemic

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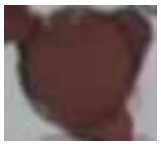
Background

The StartRight study is a multi-centre prospective study to assess utility of clinical features and biomarkers in classifying adult diabetes. It has recruited >1800 adult participants within 12 months of diabetes diagnosis at 55 UK sites and aims to complete follow-up data & sample collection by April 2023. Study outcome is determined by insulin secretion at ≥ 3 years post diabetes diagnosis, measured using C-peptide analysis on blood sample collected at final follow-up. Successful continuation of research involving blood sample collection during the COVID-19 pandemic is particularly challenging due to restrictions on visits to clinic and limited research staff capacity. The relevant ethics & sponsor approvals were granted for remote blood sample collection and C-peptide measurement from capillary (finger-prick) samples has been robustly validated.

ORIGINAL PROTOCOL FOR HOME SAMPLE COLLECTION:

Phone contact for data collection & discuss remote sample collection using absorbent card.

Participant receives study pack with instructions to collect sample independently and returns to lab



Under or over saturated samples were not viable

Aim: To increase the rate of return and viability of home finger-prick samples in a prospective multicentre study by combining a more patient-centred approach with improved sampling method.

Method

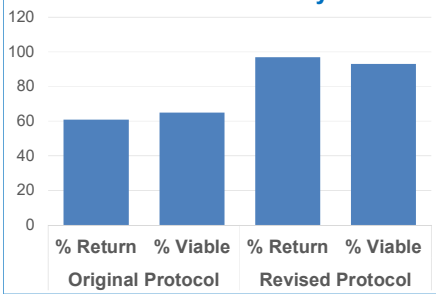
1. **We assessed the rate of home sample return and viability for analysis:** 282 participants were followed up using the original method, 173/282 (61%(95% confidence interval 55-67%) samples returned and 112/173 (65%(57-72%) were viable.
2. **We sought feedback from participants and recruiting teams:** Study participants indicated that dropping the correct amount of blood onto the card & in the right place was difficult. Those who failed to return a sample reported that they had put the pack to one side and forgotten. Discussion with recruiting teams suggested that arranging a phone appointment to support remote sample collection may help to improve sample quality and reduce the need for time consuming telephone reminders.
3. **We investigated alternative methods for sample collection,** working closely with colleagues in Exeter Blood Sciences to test and validate an alternative, more user-friendly sampling devices.

REVISED PROTOCOL FOR HOME SAMPLE COLLECTION INCLUDES:

A pre-booked remote appointment with phone support from researcher

A more user friendly Mitra® sampling device with absorptive VAMS® tip

Revised protocol results in increased rate of sample return and viability

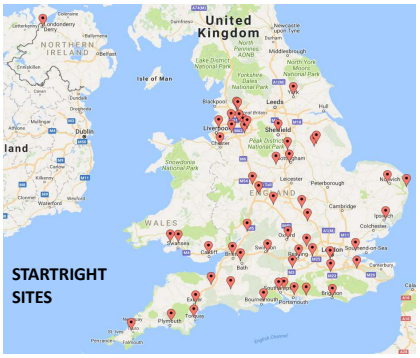


Results:

To date, 115 participants have been followed up using the improved approach, 97 (84%(76-90%) samples returned and 93 (96%(90-99%) were viable for analysis. The revised protocol & more user-friendly sample collection device has increased rate of sample return > 20% and the rate of sample viability by > 40 % of samples returned.

Conclusion:

Early results indicate that a more patient-focused approach with improved method of sample collection has lead to an increased sample rate of return and dramatically increased the % of viable samples received. Adjusting the sample collection procedure has enabled this project to continue to progress towards successful completion when on-site research visits were restricted or paused. The remote option continues to be offered as remote visits offer greater flexibility for study participation. This novel, patient-focused approach may aid other projects where samples have the stability for home collection.



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www.diabetesgenes.org/current-research/startright/