CHIEF SCIENTIST OFFICE

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RESEARCH PROJECT BRIEFING

Feasibility of 5 year follow up of participants in the Telescot diabetes trial

AIMS

A CSO funded study into telemonitoring for diabetes (where patients monitor their illness at home and share information electronically with their clinical team) showed that nine months of telemonitoring improved diabetes control. Good control is measured by the concentration of a protein in the blood called HbA1c. We wished to explore if it is feasible using clinical databases to see if this improvement was sustained by comparing more recent HbA1c levels of participants five years later. Our initial consent form did not include consent for follow-up, but if the more recent laboratory data could be retrieved within a NHS data safe haven (a specialised environment to analyse NHS data securely, maintaining patient privacy), linked to the trial participants and subsequently de-identified, five year follow up could be achieved. However, the laboratory data to determine this are scattered across several sites in England and Scotland and might require complex governance arrangements to be put in place to obtain them. This pilot study sought to determine if data held in one health board in Scotland could be successfully accrued, linked to NHS data and analysed and to see if there was any evidence of continuing effect which would justify collating the data from other sites.

KEY FINDINGS

- Retrieving the data proved much more complex than expected. As Community Health Index (the unique NHS identifier given to patients in Scotland) information had not been held in the original trial, this had to be 'seeded' using an algorithm.
- Routinely acquired data from the Scottish Care Information – Diabetes Collaboration (SCI-DC) database yielded useful data in less than 50% of cases. It was often inaccurately entered.
- Although the improved diabetes control achieved during the trial by both groups has been generally maintained there was no signal in those data that the additional benefit from telemonitoring persists after it is withdrawn

WHAT DID THE STUDY INVOLVE?

Data from the trial for Lothian participants which contained the names and dates of birth were transferred to the NHS Lothian safe haven. These were subsequently 'seeded' with the Community Health Index number by the Electronic Data and Research Information Service (EDRIS) using an identification algorithm and returned to the safe haven for linkage to the most recent measures of HbA1c from Lothian SCI DC database, hospital admissions from the SMR01 database and deaths from the General Register Office register. The data were then de-identified before the researchers were able to access them on a secure analysis server which does not permit any data to be taken away. In this way no patient identifiable data, or anonymised data left the NHS.

WHAT WERE THE RESULTS AND WHAT DO THEY MEAN?

There were 176 trial participants in Lothian (89 used telemonitoring for 9 months, 87 did not) and it was possible to link records for 170 patients. Eight of those with linked records had died within 5 years of randomisation. However, we only found follow up HbA1c measurements for 53 participants in the SCI DC database. The database also contained a number of measurements which appear to have been wrongly entered as they were outside the feasible measurement range.

The table below shows the mean (average) of the last recorded HbA1c measurement for the telemonitoring group and control group up to 5 years after they entered the trial. This difference was quite small and not statistically significant. This was tested in two ways - T-test: Mean difference -1.21mmol/mol (95% CI to -9.14 to 6.73, p=0.761). Linear regression (adjusting for baseline HbA1c and all minimisation criteria):Mean difference: -1.74 mmol/mol (95% CI -10.17 to 6.69, p=0.680)

Comparison of HbA1c for people who used telemonitoring versus those who had usual care (N=53). Last reading up to 5 years post randomisation

Allocated Treatment	N	Mean HbA1c (mmol/mol)	Std. Deviation	Std. Error Mean
Monitored	25	65.7	13.0	2.6
Not monitored	28	66.9	15.5	2.9

WHAT IMPACT COULD THE FINDINGS HAVE?

- The routinely acquired data we extracted from this database were insufficiently complete for follow-up of diabetes control. We need to investigate other sources of these data, for example general practice records
- Researchers should routinely ask research participants to permit long term follow up of laboratory data

HOW WILL THE OUTCOMES BE DISSEMINATED?

This was a pilot study to determine if a more major investigation was likely to be worthwhile. The findings concerning the usefulness of long-term routinely acquired data will be disseminated to researchers through scientific meetings. The results will be published as part of a larger follow up of participants in all the Telescot trials using deaths and hospitals admissions as outcomes

CONCLUSION

This research shows that routinely acquired data derived from the Lothian SCI DC database was of insufficient quality to determine if a telemonitoring intervention had a lasting impact on glucose control in diabetes. It underlines the importance of obtaining consent for long term follow-up of participants in randomised controlled trials which might allow direct approaches for further data.

RESEARCH TEAM & CONTACT

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The original Telescot programme, jointly funded by CSO and BUPA Foundation, was four randomised controlled trials of telemonitoring in hypertension, hypertension following stroke, type 2 diabetes and chronic obstructive pulmonary disease