characteristics. Missing data was defined as the number of randomised patients who did not contribute primary outcome data to the analysis either because it was not available or because the data was excluded.

Results

In 7/166 (4%) journal articles and 2/36 (6%) HTA monographs it was not possible to determine the levels of missing data. 141/159 (89%) and 34/34 (100%) trials had missing primary outcome data with median [IQR] levels of missing data of 5.5% [1.5, 11.0] and 11% [2.9, 19.8].

The impact of the missing data within the journal cohort meant that 454 months were wasted across 126 trials recruiting patients that did not contribute outcome data (median [IQR] per trial: 1.5 [0.7, 3.2]). Trials reported multiple reasons for missing data: patient withdrawals (64%, n = 141); patients lost to follow up (60%); investigator exclusions (53%) and failure of clinical staff to measure the outcome (45%). 91/159 (57%) imputed data and 91 (57%) trials excluded randomised patients with protocol deviations or missing data from the analysis population. 41 (26%) trials used both approaches. Abstraction of the levels of missing data was challenging. CONSORT statements were often misleading around imputation of data and did not clearly report the number of outcomes known.

Conclusion

The percentage of missing data within the leading journals was on average lower than expected. However, a comparison with the HTA monographs suggests this may reflect a difficulty publishing RCT's with missing data in the top journals. Patient withdrawal and loss to follow up were the leading causes of attrition, although the failure of researchers to measure the outcome in retained patients was cited in nearly half of the trials. Reporting missing data was often inadequate. We would recommend stricter adherence to the CONSORT flow diagram and suggest revisions to ensure that the flow diagram could be standalone with additional categories to allow distinction between the numbers analysed and the numbers for whom the outcomes were known and imputed.

P307

Identifying effective retention strategies: a research agenda

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Trials 2017, **18(Suppl 1):**P307

Background

Identifying strategies to minimise missing data was the second highest methodological research priority in a Delphi survey of the Directors of UK Clinical Trial Units (CTUs). However, a Cochrane Methodology Review of nested randomised studies of missing data strategies shows a substantial evidence gap. The review demonstrates an emphasis on improving questionnaire response rates and an absence of evidence that address the full range of causes of missing data. In addition, published case studies frequently describe the use of strategies which have not been evaluated. Our aim was to assess current retention practices within the UK and identify priorities for future research to evaluate the effectiveness of strategies to reduce attrition. Methods: 75 Chief Investigators of National Institute of Health Research Health Technology Assessment (NIHR HTA) funded parallel randomised control trials starting between 2009 and 2012 and 47 UK Clinical Trial Units (CTUs) were surveyed to identify what approaches and strategies were used to mitigate missing data in trial design and conduct.

Responses from the current practice survey were used to inform a subsequent two round Delphi survey with CTUs to gain consensus around research priorities to assess the effectiveness of missing data interventions.

Results

50/75 (66%) Chief Investigators and 33/47 (70%) CTUs completed the current practice surveys. 78% of Chief Investigators were aware of retention challenges and implemented strategies at trial design. Patient initiated withdrawal was the most common cause of missing data. CTUs routinely used newsletters, timeline of participant visits, and telephone reminders to mitigate missing data. CTUs reported evaluating 36 of the 59 strategies presented using nested studies or a comparison of retention before and after implementation. However, some frequently used strategies such as site initiation training have had no research to inform practice.

35 CTUs (74%) participated in the Delphi survey of which 34 (97%) completed both rounds. Pre-defined consensus was reached on seven topics. Six retention strategies met consensus that further research was of critical importance: site initiation training; frequency of patient contact during a trial; the use of routinely collected data; the frequency and timing of reminders; triggered site training and the length of time needed to complete questionnaires. In contrast, 82% reached consensus that research into the effectiveness of Christmas cards for site staff was of low importance.

Conclusion

The survey of current practices demonstrates a variety of strategies are being used to mitigate missing data but with little evidence to support their use. This Delphi survey has identified a consensus of research priorities to be evaluated.

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Optimising the recruitment of underrepresented ethnic minority patients to telehealth diabetes trials: examining the role of language and research reporting practices

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Trials 2017, **18(Suppl 1):**P308

Background

Randomised controlled trials (RCTs) are often considered the gold standard of health intervention research. However, most RCTs underrecruit ethnic minority patients, potentially jeopardising the external validity of their findings. One recruitment challenge relates to assessing whether patients have sufficient language proficiency to provide informed consent and engage with the intervention. However, little is known about how trial recruiters assess potential participants' language proficiency. Using diabetes telehealth intervention RCTs as a case study, we investigated the proportion of published trials that include language proficiency as part of their inclusion criteria, including how and why they do so. A secondary objective was to explore any links between the inclusion of language-related eligibility criteria and the proportion of ethnic minorities recruited.

Methods

A systematic review was conducted on telehealth intervention RCTs that focused on type 2 diabetes and excluded ethnically-targeted studies. Two reviewers independently conducted abstract and full-text screening, risk of bias assessment, and data extraction.

Results

Of 3358 records identified in the search, 79 articles consisting of 58 distinct RCTs were included in the review. Half of the included RCTs (29/58) referred to patients' language proficiency as an eligibility criterion. However, there were no common procedures across RCTs to determine if patients had the requisite language ability to participate. Whereas some studies listed different combinations of language skills as being necessary (speaking, listening, reading, writing), others referred to patients' need to be native speakers. In two RCTs, there was a mismatch between the telehealth medium used and the language skills cited (e.g., telephone intervention requires writing but not speaking ability), whereas four underspecified the language skills required (e.g., speaking but not reading ability stated as necessary for a telephone and computer-text intervention).

The 29 RCTs that referred to language as a patient eligibility criterion tended to be larger-scale, recruiting nearly 1.7 times the total number of recruited patients, compared to the 29 RCTs that made no reference to language at all. Twenty-one RCTs in the former group and 17 in the latter provided ethnicity information and

recruited a median of 24.6% versus 18.0% ethnic minority patients as a proportion of the total sample respectively. The RCTs that included language proficiency as an eligibility criterion recruited a greater proportion of ethnic minority participants (37.8% of all recruited participants) compared with those that did not (13.9%).

Conclusions

Approaches for assessing patients' language proficiency were found to be inconsistent in the context of diabetes telehealth intervention RCTs. Studies referring to language in patient screening might report more on ethnicity because some ethnic minorities are also linguistic minorities. Or it may be that these studies are more robust in terms of research reporting and sample size. There was no evidence that reference to language screening is associated with lower participation from hard-to-reach groups, although the soundness and consistency of individual inclusion/exclusion decisions on language grounds could not be ascertained. Future research should focus on developing and validating a language assessment tool that could be consistently applied across RCTs to screen patients' language proficiency during recruitment.

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Does appearance matter? A study within a study

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Trials 2017, **18(Suppl 1):**P309

Background

A central tenet of recruitment to clinical studies is that participants take part freely, armed with full information about the study. There has been little research into how the appearance of the information may affect recruitment. A study of Patient Information Leaflets (PILs) concluded that PILs need 'to be well structured and designed in an appealing manner'. These aspects have not yet gained sufficient attention [1]. In the case of paper information leaflets, production of a high quality attractive leaflet is possible, but may require specialist software, and incur extra costs for colour printing. Without the evidence of benefit, the additional resources may not be justified.

Methods

To investigate if the appearance of pils affects recruitment, we chose to embed a randomised controlled trial (RCT) within the Outcome Monitoring After Cardiac Surgery (OMACS) study. OMACS uses routine NHS data alongside participant questionnaires, and consent is sought by post at 3 months post-surgery. OMACS was chosen as the 'host' study as around 120 patients are approached for participation per month, allowing evidence to be collected quickly. Participants are randomised to receive one of 3 PILs: a tri-fold coloured leaflet produced using a graphic design package, indesign, (PIL A), a coloured A4 sheet produced in Microsoft Word (PIL B), and a standard A4 black and white sheet (PIL C). Both coloured leaflets are printed professionally. The information contained in each leaflet is identical and participants do not know about the randomised element of OMACS. The sample size is 1590 which, assuming a consent rate of 70% (based on a previous similar postal questionnaire study that achieved this (personal communication)), will provide 90% power to detect a 10% difference in consent rate between any pair of PIL formats, with an overall significance level of 5%.

Results

After 5 months, we have sent out 436 invitation letters and have 182 consented participants. Consent rates for each PIL are: A - 68/181 (38%) B - 76/180 (42%) C - 76/180 (42%) An unexpected finding is that consent rates are much lower across the study than was anticipated. We are currently investigating possible reasons for this. If the current trend continues we will review the implications for the sample size and power of the study.

There are a number of differences between OMACS and the previous study which may explain the difference in response rates. Previously, the timing of the approach for consent is different (1 year versus 3 months) and patient packs were simpler with fewer documents than used in the OMAC study. In attempt to cater for participants' preferences, OMACS invites participants to elect for alternative response methods (e.g. Postal versus internet questionnaire) and also allows them to opt out of some aspects of the study. The previous study did not include this diversity of options.

Conclusion

At this early stage, no formal conclusions can be drawn as to the effect of the appearance of the PIL. One year results with a formal comparison between the rates of each group will be presented.

Reference

1. Reinert, C., et al., Quantitative and qualitative analysis of study-related patient information sheets in randomised neuro-oncology phase III-trials. Eur J Cancer, 2014. 50(1): p. 150–8.

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Reducing missing data in palliative care randomised controlled trials: a mixed-methods study

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Trials 2017, **18(Suppl 1):**P310

Background

To reduce the risk missing data (MD) pose to the power, precision and validity of trial findings, MD should not only be handled appropriately at the analysis stage, but more importantly potentially reversible MD risk factors must be identified and modified at the design and conduct stage. This mixed-methods study used palliative care trials, where MD due to death and disease progression are expected, to explore the association between primary outcome MD and participant, trial site and trial-level MD risk factors.

Methods

(i) Trial-level factors: systematic review and meta-regression of primary outcome MD in 108 palliative care trials; (ii) Participant and site-level factors: multi-level cross-classified modelling using individual participant-level data (IPD) from 10 multi-site trials; (iii) Identification and exploration of factors in more depth: thematic analysis of interviews with 27 research personnel and participants.

Results

(i) Systematic review: MD was associated with increasing numbers of questions/tests requested (odds ratio (OR) 1.19 per-doubling, 95%CI 1.05, 1.35) and longer study duration (OR 1.09 per-doubling, 95%CI 1.02, 1.17). (ii) IPD: At the participant-level (n = 1,846), MD was associated with baseline missingness (OR 17.19, 95%CI 8.55, 34.53) and poorer Karnofsky Performance Status (10-unit increase: OR 0.78, 95%CI 0.70, 0.87); at the site-level (n = 35), MD at the end of follow-up was associated with sites that randomised a greater number of participants (per 10-randomisations: OR 1.08, 95%CI 1.01, 1.16) and with fewer research personnel (4 personnel compared to 1: OR 0.07, 95%CI 0.01, 0.84). (iii) Interviews: themes included "attention-to-detail vs. attention-to-person", "clinical vs. research-role tension", and "beyond GCP training".

Conclusion

There is the potential to reduce MD in palliative care trials by modifying the factors associated with MD identified from this study. Further development of the theoretical framework is required, prior to developing an intervention to reduce MD that will be tested within trials.