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Trials

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Abstract omitted

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Some practical considerations in the design of multi-arm multi-stage designs

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Introduction: In the design of cancer clinical trials, one is often concerned with a number of options in the event that several treatments are of interest.
Methods: We explore in this work the distinct possibilities when four treatments are available, one acting as control and three as potentially efficacious alternatives. This design may be embedded within the context of multi-arm multi-stage (MAMS) trials where one may select a two- or three-stage design.
Potential Results: We explore the application of such designs, including trade-offs between potential gains in the number of patients with additional stages contrasted with patients "lost" due to practical considerations such as patients randomised in dropped arms while waiting for interim analyses and inspection by an Independent Data and Safety Committee. In addition, in cancer studies one may focus on the primary end-point using a time-to-event analysis or a binary outcome by looking at the probability of (potentially progression-free) survival at a specific, clinically meaningful, time point. The effect of such choices is extensively investigated.
Potential Relevance & Impact: We conclude with a discussion of the available software for MAMS designs and their advantages and disadvantages in terms of accuracy.

P-3
The UK plasma based Molecular profiling of Advanced breast cancer to inform Therapeutic CHoices (plasmaMATCH) Trial: A multiple parallel-cohort, phase IIa platform trial aiming to provide proof of principle efficacy for designated targeted therapies in patient subgroups identified through ctDNA screening (CRUK/15/010)

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Trials 2019, **20(Suppl 1):**P-3

Introduction: plasmaMATCH is a novel platform trial which assesses the potential of circulating tumour DNA (ctDNA) screening to direct targeted therapies in advanced breast cancer (ABC) patients. The trial recruited ahead of target and will report initial results within 3years of first patient first visit demonstrating efficiency of this design.
Methods: plasmaMATCH is an open-label, multi-centre phase IIa platform trial, consisting of a ctDNA screening component and five parallel treatment cohorts. Patients with an actionable mutation identified at ctDNA screening are invited to enter Cohorts A-D to receive a targeted treatment matched to the mutation identified (A: ESR1–extended-dose fulvestrant; B: HER2–neratinib+/-fulvestrant; C&D: AKT1 (or PTEN for Cohort D) –AZD5363+/-fulvestrant). Cohort E was added

prevent adverse drug reactions looking more and more likely. It is essential that the views of the public are included in this advancement. We are designing an experiment to measure the general public's opinions about genetic testing to prevent adverse drug reactions. This will take the form of a discrete choice experiment (DCE), a survey design which allows us to quantify preferences.
Methods: A DCE requires participants to 'trade-off' different aspects of genetic testing. For example, we may find that people are willing to wait an extra month to receive results if the accuracy of the test was higher. Using this design allows us to provide quantitative answers to the question of public preferences.
To ensure the generalisability, relevance, and accuracy of results, qualitative work to inform DCE development is essential. We are planning to use online questionnaires with a patient group and with clinicians, followed up with focus groups with the general public. We are hoping to use a market research company to administer the survey, as they have access to a UK-representative panel and can return results within 48 hours.
Timing of Potential Results: At the time of abstract submission, we are awaiting ethical approval to begin the study. Once this is received, we anticipate spending 3 months on qualitative work, and 2 months for data analysis.
Potential relevance and impact: We are doing this to ensure that the views of the general public are heard and can inform future developments in personalised medicine. Quantifying using a DCE provides clear results to policy-makers and clinicians. This increases the likelihood of public acceptance of personalised medicine interventions.

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Public involvement beyond clinical research studies

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Background: Public involvement as advisors in health research studies is becoming an established norm. However, scrutiny of the literature indicates that public involvement is predominantly described in clinical evaluation studies, such as trials of medical interventions. The value and role of public involvement in studies which are theoretical or methodological, such as the development of new statistical methods, are less well reported. We aimed to explore the value of having public advisors on these types of studies where, in contrast to clinical studies, their input is not drawing on patient experience.
Methods: A qualitative study, using focus groups with members of the public and with researchers, was used to explore the perceived role and value of public advisors in types of health research which are not clinical research studies. Focus groups were recorded, and transcribed, and qualitative data analysis software was used to systematically store and retrieve data during thematic analysis.
Results: Fifteen public and nine researcher participants took part in the study. Examination of the data suggested themes relating to potential benefits from public involvement; challenges to involvement; and opportunities provided. The data indicated potential for public involvement at different stages of the research cycle in all studies, including those which are more theoretical or methodological in nature, such as methods development in clinical trials.
Discussion: Involving the public as advisors in all forms of research adds value, and the study confirms that involvement should not be confined to research evaluating clinical interventions. The study provides information for health researchers in areas where public involvement may be less established, such as methods development in clinical trials. Involvement in these research areas has the potential to add diverse forms of knowledge, provide legitimacy, and aid impact.

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Co-designing a virtual world with young service users to deliver social cognition therapy

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Introduction: Involving service users in the design and conduct of research has been encouraged in government policy, but it is rarely achieved, especially at trial initial stages. Co-design implies genuine partnership in the generation of knowledge between service users and researchers. This paper shows a step-by-step co-design approach used to adapt an existing manualised social cognition intervention for people with a first episode of psychosis to a virtual world environment.
Methods: Clinical researchers, IT programmers and a group of young people who have used mental health services were invited to participate in the design of a virtual environment to deliver an accessible social cognition intervention to a hard to engage service user group. An iterative process between service users and the design team was set up and included developing initial ideas, creating a prototype and testing the virtual world.
Results: Twenty young service users of local mental healthcare services participated in the design and planning of intervention delivery. Young people felt the virtual environment should be familiar, urban spaces, akin to therapy rooms or classrooms they have used in real-life situations rather than non-traditional therapy spaces that were initially proposed. Findings reflected the demographic makeup of the sample.
Discussion: After the co-design process, the specific design, approach and protocol was tested in a proof-of-concept trial with young people who experienced a first episode of psychosis. Young service users were integral to an agile and iterative design. Technological innovations should be routinely co-designed and coproduced if they are to realise their potential to deliver acceptable and affordable mental health interventions.

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The benefit of a Lived Experience Advisory Panel (LEAP) in the design and conduct of a clinical trial into depression

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Introduction/Aims: This trial is investigating Transcranial Magnetic Stimulation (TMS) as a treatment for patients with moderate to severe treatment resistant depression. From the outset the research team were keen to involve service users or carers with lived experience of managing depression, in order to optimise engagement with, and retention of participants.
Methods: Throughout the trial set up and current phase of recruitment we have imbedded LEAP in all activities by: -scheduling ongoing quarterly (LEAP) meetings; involving members who either have received TMS treatment, participated in previous TMS trials, or have experience of treatment resistance depression, all local to the