country, attendance to intervention sessions and associated trial clinician, as well as clinicians' characteristics such as gender, age, country, profession and years of clinical experience will be collected. Furthermore, the date, duration and mode of conducting the interview/focus group will be collected. Intensive training in qualitative research was provided to ensure a consistent approach across the research team. Interviews and focus groups with patients and clinicians began after completion of outcome assessment and final interventions session, respectively. Data collection began in April 2020 and is ongoing at the time of submission of this paper. Due to restrictions related to COVID-19 pandemic, our initial plan to conduct face-to-face focus groups and interviews with clinicians and patients, respectively, was changed to remote data collection by means of semi-structured phone/video conference interviews. Researchers are conducting face-to-face focus groups with clinicians where restrictions have been (partially) lifted.

The topic guide for focus groups with clinicians was developed to explore a) experience of intervention delivery; b) perceived usefulness/effectiveness of DIALOG+; c) views on collaborative working between patients and clinicians (novelty of the intervention) and d) views on sustainability of the intervention and how it could be scaled up in clinical settings if shown to be effective. The topic guide for interviews with patients was developed to explore participants' a) experiences of engaging with the DIALOG+ intervention; b) perceived impact of DIALOG+ on their life; c) views on collaborative working between clinicians and patients; d) views on sustainability of the intervention and how it could be scaled up in clinical settings if shown to be effective and e) suggested improvements to the intervention. The topic guide questions specifically focus on clinicians' and patients' views about the key distinctive elements of the intervention, such as setting actions at the end of each DIALOG+ session and collaborative working. The topic guides were developed in English by a multidisciplinary, multilingual team using an iterative process which included circulating draft versions among all team members and patient representatives. Discussions were held among researchers from the different countries to ensure a shared understanding of the topic guide items. The final versions of the topic guides were then translated into the national Southeast European languages by prioritising translation of the meaning of the topic guide items rather than word-for-word translations, in order to make the questions contextually appropriate using everyday language.

The end-of-trial qualitative study will enable us to explore participants' experienced acceptability of the intervention and in turn will help to explain the overall effectiveness of the intervention. Data collection is likely to highlight challenges in the implementation across the different contexts as well as patients' and clinicians' views of the way DIALOG+ works in practice. It is also likely to generate further hypotheses (in addition to those proposed by Omer et al., 2016) about the mechanisms of action of DIALOG+.

Data analysis: Descriptive statistics will be used to report participant characteristics. Qualitative data analysis coordinating teams will be formed, consisting of one representative from each country's research team and one from the team in the UK in order to establish equal partnership among all the participating countries. Focus groups and semi-structured one-to-one interviews will be audio-recorded, transcribed verbatim, anonymised and analysed. Data will be coded into a pre-determined coding framework based on the constructs of the TFA (Sekhon et al., 2017). The transcripts will be analysed using framework analysis (Ritchie & Spencer, 1994; Krueger & Casey, 2000; Rabiee, 2004), using the following steps:

- Researchers will familiarise themselves with the translated transcripts through listening to interviews and focus groups, reading and coding transcripts and discussions in data analysis coordination meetings.
  - 20% of all interview/focus group transcripts from each participant group will be translated into English, so that researchers from all countries can actively collaborate. The translations will be conducted by the researchers who facilitated the interviews or by professional translators in which case the researchers will double-check the translations for accuracy. Meaning-based translations were prioritised, as opposed to word-for-word translations because not every word or expression is universal and translatable. The majority of transcripts will remain in their original languages to reduce the possibility of mistranslation and loss of shades of meaning.
- Developing a coding framework through which our data could be organised.
  - A framework will be developed in English, incorporating the TFA constructs (Sekhon et al., 2017).
- Indexing the data through systematically coding each 'chunk' of text from the transcripts to one (or more) of the categories in the framework.
  - Each Southeast European team will conduct this step using transcripts in local languages.
- Charting the data which involves summarising the data in each category for each participant into a table. The summary of the data will be in English. Variability in participants' accounts associated with their individual characteristics, as

specified in the data collection procedures, will be captured by charting.

- Mapping and interpretation
  - Only key quotes, determined by the relevant Southeast European teams, representing the themes identified, will be translated into English and used to report the findings. We will report any differences in patterns of data and will explore possible associations with differences in attributes of context.

RQDA software (Huang, 2016) will be used to facilitate this process. As part of 'thematic' approaches, framework analysis allows for flexibility and structure to management and analysis of data. This fits with the current study due to the already determined research aims, large sample size and large research team from six different countries. Additionally, framework analysis allows for *a priori* issues and emergent data-driven ones to direct the development of the analytic framework, by developing an initial framework that is more focused on researchers' *a priori* concerns or research questions, which is then piloted on the transcripts to refine the *a priori* categories to also best fit the data (Parkinson et al., 2015). This will allow us to explore emerging changes in implementation and unanticipated or complex causal pathways.

The final stage of the process evaluation analysis will be to bring together the findings from the broader quantitative and qualitative methods to generate hypotheses about why the intervention did (or did not) work in all or some contexts and about the intervention's mechanisms of action, as well as to identify implications for longer term implementation if appropriate.

DISCUSSION

This paper describes the rationale and methods for the planned mixed-methods process evaluation of the IMPULSE trial. This process evaluation builds on findings from the process evaluation of the DIALOG+ trial in the UK (Omer et al., 2016) that focused on suggesting the mechanisms of DIALOG+. We will conduct a comprehensive exploration of the contextual factors that may have impacted the intervention's effectiveness, and of the fidelity and acceptability of the intervention in a range of healthcare settings. The differences between these settings and the UK are potentially important; we will systematically investigate context as a potential effect modifier. This research may also contribute to further understanding of the value of process evaluations in the context of clinical trials in mental healthcare.

The process evaluation of the IMPULSE trial will provide an insight into the trial's validity. Figure 3 illustrates the proposed explanatory pathway for the process evaluation of the IMPULSE trial. Firstly, this process evaluation will yield evidence about multiple component constructs of intervention acceptability of clinicians and patients who participated in the intervention arm of the trial. Secondly, it will provide a greater understanding of intervention fidelity during the trial. If clinicians perceived the intervention as highly acceptable, then it is likely that they delivered the intervention according to the manual. Similarly, if patients' experienced intervention acceptability is found to be high, we can expect that they were more likely to engage with and enact the intervention as intended. Additionally, the findings of the process evaluation may show differences between the DIALOG+ intervention and TAU. Hence, exploring fidelity will show if the trial result reflects a valid evaluation of the DIALOG+ intervention as designed. Importantly, different attributes of the context in which DIALOG+ was implemented during the IMPULSE trial will be considered as part of the process evaluation because of the possible impact on variations in intervention acceptability, fidelity and outcome measurement. Therefore, the findings from this process evaluation will be used to explain the effectiveness or ineffectiveness of DIALOG+ and how attributes of context could modify the effects of the intervention.

The study has several strengths and limitations. The adoption of a mixed-methods approach and triangulation of data sources (healthcare provider, patient) and data type (qualitative, quantitative) can be considered as a key strength. Integration of the different data sources enhances the knowledge that this study can yield by achieving a 'whole greater than the sum of the parts' (O'Cathain et al., 2010). The qualitative and quantitative methods will assess different aspects of the overall research question and bringing them together will generate a more thorough understanding of how the DIALOG+ intervention works and the factors that may modify its effects. Process evaluation data will be analysed prior to awareness of the trial outcomes, which minimises interpretation bias. A limitation is that participants in the semi-structured interviews will only be a subset of all trial participants. Whilst we will ensure that participants with different characteristics are included, there is a risk of selection bias and possibly, we will not be able to interview enough participants who withdrew from the trial. Additionally, not all clinicians and patients from the trial consented for at least one of their intervention/control sessions to be audiotaped, which poses a risk of sampling bias.

We will perform exploratory analysis of differences and similarities between countries included in the trial hoping that

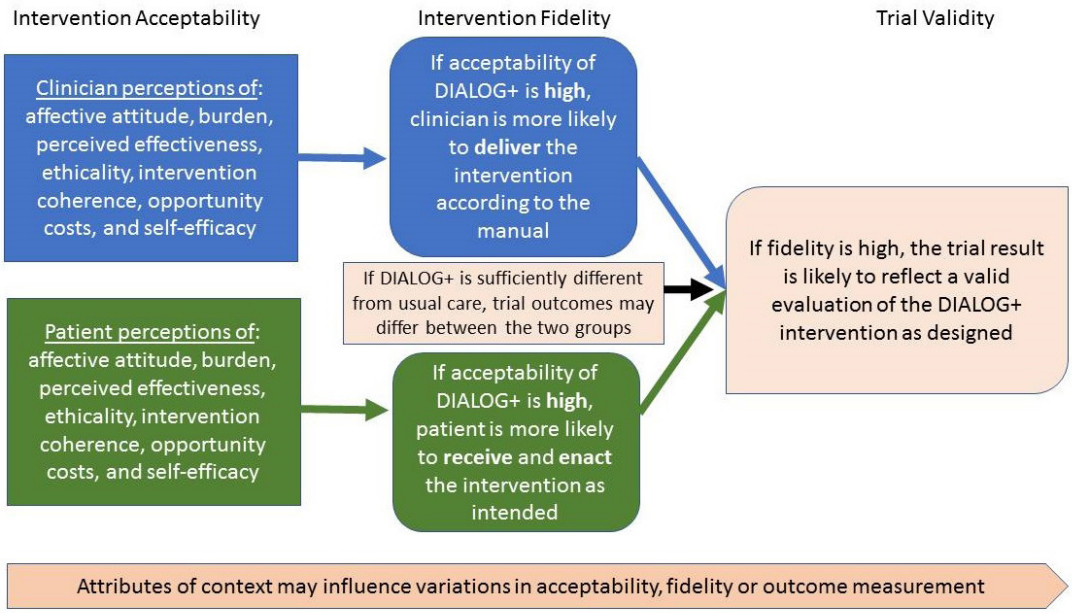

Figure 3. Proposed explanatory pathway for the process evaluation of the IMPULSE trial

this work could provide additional insights into the studied topics and possibly generate hypotheses for future studies. We will propose how further monitoring and research could be used to enable healthcare systems in these countries to track sustainability of the use of DIALOG+ over time and the potential long-term effects on patients and the mental healthcare workforce. Findings will be disseminated via a final report, peer-reviewed publications and practical guidance for healthcare professionals, commissioners and policymakers.

DECLARATIONS

Ethical Approval

All procedures described in this protocol are in accordance with the ethical standards of the institutional and/or national research committee and with the 1975 Helsinki declaration and its later amendments or comparable ethical standards. All procedures were approved by the following ethics committees (in alphabetical order): Bosnia and Herzegovina (Klinicki Centar Univerziteta u Sarajevu – Eticki Komitet 03-02-4216, Eticki komitet JU Psihijatriska bolnica Kantona Sarajevo & JU Zavod za bolesti ovisnosti Kantona Sarajevo 02.8 – 408/19), Kosovo[4] (Hospital and University Clinical Service of Kosovo – Ethics Committee 2019-85), Montenegro (Javna Zdravstvena Ustanova Klinicki Centar Crne Gore – Eticki komitet 03/01 – 29304/1, ZU Specijalna Bolnica za Psihijatriju 'Dobrota' Kotor – Eticki komitet, Eticki Komitet JZU Dom Zdravlja 'DR Nika Labovic' Berane 01-47), Republic of North Macedonia (Eticka Komisija za istrazuvanje na luge, Medicinski Fakultet pri UKIM vo Skopje 03-24219), Serbia (Eticka komisija Medicinskog fakulteta u Beogradu 2650/XII-20 and Eticka komisija Specijalne bolnice 'Dr Slavoljub Bakalovic' Vrsac 01-36/1) and the United Kingdom (Queen Mary University of London QMREC2204a, 16 October 2018).

4 By United Nations resolution.

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Informed consent

The information about informed consent is taken from the IMPULSE trial protocol (Jovanović et al., 2019). All study participants were asked to sign an informed consent form prior to their participation in the study. The patients who agreed to be involved in the study met with researchers who checked if patients met the eligibility criteria and invited them to sign a consent form. Researchers explained the study to the patient and provided all relevant information, including the risks, benefits and confidentiality. Once a patient signed the informed consent,

researchers proceeded to complete the baseline assessment. Participating patients received their routine treatment from the mental healthcare systems in their area and/or according to their local health insurance arrangements. In the unexpected event that any patient appeared highly stressed or upset, the researchers were instructed to terminate the research activity and contact a clinician.

Study registration

The IMPULSE trial was registered with ISRCTN on 29/03/19 (ISRCTN11913964).

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