

# Towards Horizon 2020: challenges and advances for clinical mental health research – outcome of an expert survey

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**Background:** The size and increasing burden of disease due to mental disorders in Europe poses substantial challenges to its population and to the health policy of the European Union. This warrants a specific research agenda concerning clinical mental health research as one of the cornerstones of sustainable mental health research and health policy in Europe. The aim of this research was to identify the top priorities needed to address the main challenges in clinical research for mental disorders.

**Methods:** The research was conducted as an expert survey and expert panel discussion during a scientific workshop.

**Results:** Eighty-nine experts in clinical research and representing most European countries participated in this survey. Identified top priorities were the need for new intervention studies, understanding the diagnostic and therapeutic implications of mechanisms of disease, and research in the field of somatic-psychiatric comorbidity. The “subjectivity gap” between basic neuroscience research and clinical reality for patients with mental disorders is considered the main challenge in psychiatric research, suggesting that a shift in research paradigms is required.

**Conclusion:** Innovations in clinical mental health research should bridge the gap between mechanisms underlying novel therapeutic interventions and the patient experience of mental disorder and, if present, somatic comorbidity. Clinical mental health research is relatively underfunded and should receive specific attention in Horizon 2020 funding programs.

**Keywords:** clinical research, mental health, randomized clinical trials, Horizon 2020, expert survey, challenge, research agenda, Europe

## Introduction

Given the sizeable burden and costs associated with mental disorders,<sup>1-6</sup> the European Union has called for a systematic approach toward research in this area. The “ROADmap for MEntal health Research and well-being in Europe” (ROAMER) project, funded by the European Commission’s Seventh Framework Programme, was given the task of developing a mental health research roadmap based on expert consultation covering various domains in the field (ie, psychological research, biomedical research, research funding, infrastructures, and capacity building, research on social and economic aspects, and research on well-being and public health), as well as on the views of other stakeholders, such as service users, carers, professionals, and policy and funding institutions.<sup>7</sup> Several work packages within ROAMER have already published about their priorities, such as public health research needs for improvement of mental health in Europe,<sup>8</sup> the core aspects of biomedical and psychological mental health research and their possible role in diagnosis and treatment of mental disorders,<sup>9-13</sup> as well as the views of national

associations/organizations of psychiatrists, other mental health professionals, users and/or carers, and psychiatric trainees in the 27 countries of the European Union about the priorities for mental health research in Europe.<sup>14</sup> Subsequently, within ROAMER, clinical mental health research was recognized as an area of particular interest, given the growing gap between the enormous output of neuroscience research and the actual impact of research on clinical treatment for patients with mental disorders.<sup>15</sup> Clinical mental health research aims to translate such research findings by applied research aimed at improving the health of individuals with mental disorders and thus is required to bridge this gap. Current treatment of mental disorders usually requires complex and multilevel interventions targeting morbidity and mortality reduction, ie, prevention of suicide,<sup>16,17</sup> detection and treatment of mental disorders by consultation models,<sup>18,19</sup> and collaborative care models integrating primary care and specialty mental health care,<sup>20</sup> and by integrating psychopharmacological, medical, psychotherapeutic, psychological, system, and societal interventions aimed at return to functioning and work with systems of care delivery. Clinical mental health research thus requires a multidisciplinary approach and a translational perspective. A research agenda exploring gaps and challenges, as well as the actions needed to address these challenges, is warranted. Therefore, the Clinical Research Task Force was established within ROAMER in order to perform such a survey, addressing these issues among experts in the field of clinical mental health research. The findings of the first round of this survey are presented in this paper.

## Materials and methods

### Procedure

The survey aimed to gain an insight into the challenges, gaps, and advances needed in clinical research in the field of mental disorders. It was performed among experts in this field and consisted of two rounds. The first round, performed from February to April 2013, aimed at setting priorities for mental health research, and the second round, performed from July to September 2013, focused on consensus among the experts. It was a web-based survey using Webropol 2.0 online survey and analysis software.<sup>21</sup> Experts were asked to follow an individualized survey link to read the informed consent statement and to participate. The link was unique to each putative participant, and could not be forwarded to anyone else. Nonrespondents received reminder emails every third day and were approached by ambassadors and personal contacts from the ROAMER Clinical Research Taskforce in each country. The results of the first round were discussed

during a scientific workshop in Amsterdam, March 18, 2013, in which the Clinical Research Task Force consulted experts in the field of clinical research on mental disorders. The current paper reports the results of the first round of the expert study as well as the results of the scientific workshop in Amsterdam. Analysis of the first round of the survey resulted in selection of main challenges as well as in prioritizing of the advances required to address these challenges, which are presented in the Results section. Discussions during the scientific workshop provided us with a broader perspective to interpret the findings of the first round of the survey, described in the Discussion section of this paper.

### Selection of participants

In total, 313 experts in clinical mental health research were invited to participate, beginning on February 21, 2013 through April 8, 2013. They were selected by the members of the ROAMER Clinical Research Task Force according to one of the following criteria:

- minimum h-index of 10 in Web of Science,<sup>22</sup> or more than 50 publications in the field in Web of Knowledge
- experts who had been consulted in the Grand Challenges in Global Mental Health survey,<sup>23</sup> who were scrutinized in duplicate (RK, CMFC) in order to identify all European experts involved in clinical research
- principal investigators carrying out clinical research in Europe were selected (RK, SK) from several databases for clinical research, such as the <http://www.trialregister.nl/trialreg/index.asp> trial register and the Web of Knowledge; the search terms used were in concordance with those used for other ROAMER activities and are shown in the Supplementary material
- from the list of experts already consulted by ROAMER in lieu of other surveys, the experts who published on clinical research topics in the Web of Knowledge in the last 5 years were selected (CMFC)
- ROAMER Clinical Research Task Force members were asked to list the most important experts from their own network using the same criteria
- in order to involve experts from as many European countries as possible, and thus attain sufficient representation in the survey with experts from all over Europe, members of ROAMER from countries with low representation, taking into account criteria 1 to 5, were asked to suggest experts meeting these criteria (DL, KW)
- ROAMER work package leaders involved in clinical research as well as the coordinator of ROAMER were also invited to participate.

## Survey questions

The first round of the survey consisted of three sections: first, there was an open-ended section with questions on challenges and advances needed, followed by a section listing a priori challenges that the experts were asked to rate, and finally, an open section in which experts could propose advances that were required in order to address the challenges.

### Section I: open question on challenges and advances

The expert survey started with a definition of a challenge in clinical research: “In line with previous initiatives, a challenge in clinical research is defined as “a specific barrier that, if removed, would help to solve an important health problem. If successfully implemented, the intervention(s) could lead to a high likelihood of feasibility for scaling up and impact.”<sup>11</sup> Subsequently, the experts were asked an open-ended question on perceived challenges in the field of clinical mental health research, as follows: “Please list your core challenge in Clinical Research on Mental Health and Well-Being in Europe – irrespective of any specific disease area or age group.” The experts could list up to five such challenges.

### Section II: a priori gaps and policies

In addition to the open-ended section on challenges, the first-round questionnaire also included 23 a priori general gaps, nine a priori methodological gaps, and ten a priori possible policies required to close those gaps identified by the Clinical Research Task Force and the ROAMER board, based on preliminary expert consultation (SK, CMFC). Experts participating in the survey were asked to rate these gaps using close-ended questions as follows. For the general gaps, the response could be chosen from: 1 (I do not see this as a gap), 2 (no priority), 3 (modest priority), and 4 (high priority). For the methodological gaps, the response could be either 1 (I do not see this as a gap) or 2 (I do see this as a gap). For the ten possible policies required to close gaps and advance challenges in clinical research, the possible responses were: 1 (I do not agree), 2 (I half-half), and 3 (I fully agree). Experts could not skip through or go back through the survey, so contamination of section 1 with items of section 2 could not occur and the rate of missing data was limited.

### Section III: open questions on advances and their prioritization identified by experts

The last section contained open-ended questions prompting the experts to choose the three highest rated challenges from

the first two sections, and to suggest advances to address these challenges. Input was provided by a member of the Scientific Advisory Board on how to conduct surveys and how to interpret their results.<sup>24</sup>

## Analysis

The first open-ended question section resulted in a range of items (challenges) that survey participants evaluated as suitable for prioritization in clinical research. Items were categorized into twelve categories (themes) in duplicate and independently by two post-doctoral researchers (IE, SK). Duplicates and redundancies were removed (IE, SK). The Webropol survey program calculated means in the event of more than two-item scales, or percentages in the event of two-item scales, and provided the expert ratings on the respective a priori challenges and policy advances. Qualitative analysis of the data from the three sections of the questionnaire was done to identify the highest priority general challenges and advances for clinical research, and the highest priority methodological challenges, rated as such by the experts. These were subsequently discussed with the experts during the invitational conference.

## Results

### Participants

A total of 313 experts were invited for participation. Of these, 105 (34%) were identified as having accessed the system; an unknown number of experts did not receive the emails containing an invitation for and access to the survey. Of the 105 respondents identified to have accessed the website for the survey, 89 (response rate 85%; 28.4% of all those invited; 79% male respondents; mostly aged >50 years) from a variety of European countries participated in the first round of the survey. The respondents represented almost all European countries, with an overrepresentation of the Netherlands and the UK, which are the most productive countries in terms of clinical mental health research, particularly in randomized controlled trials (Figure 1).

Respondents were mostly psychiatrists, psychologists, general physicians, and some occupational physicians who represented different areas in the field of clinical research. The best represented areas were clinical trials (71%), epidemiology and public health research (41%), health services research (34%), and basic research (30%). Experts represented different professional grades, disciplines, and institutions, with an overrepresentation of professors (74%) working at universities or in university hospitals (86%).

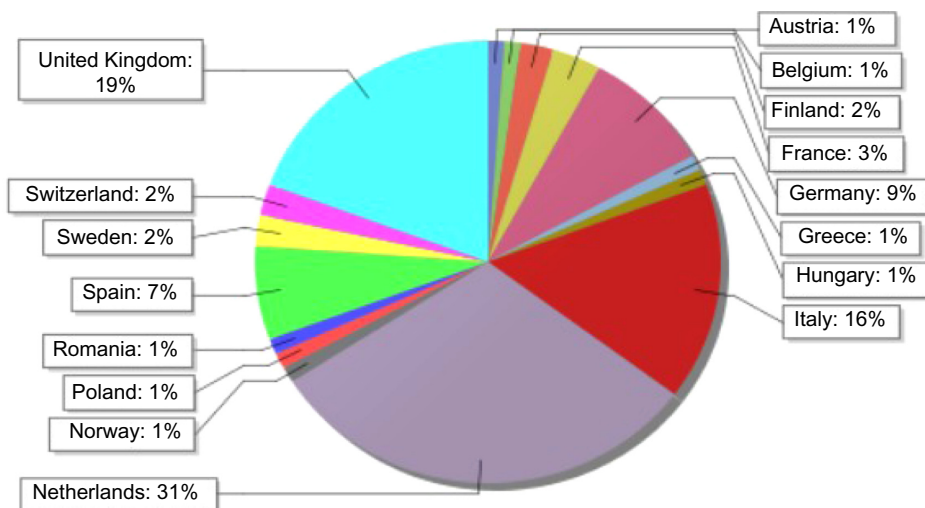


Figure 1 European countries represented by the sample of respondents.

### Challenges

Challenges identified regarding the open-ended questions in section I were reduced to 12 categories, and qualitative analysis showed substantial correspondence in challenges suggested by the experts in section I and the a priori-defined gaps and challenges in section II. Ratings of the experts for the predefined challenges therefore could be used to prioritize the combined challenges in sections I and II. The priority rating of the general challenges ranged from 2.6 to 3.6 in the 23 general items, and the total mean was 3.04. Items in the upper half above the mean rating of the priority ratings thus were items with a priority of 3.3 or more. These are shown in Table 1.

The priority rating of the methodological challenges ranged from 2% to 73% in the eleven items. The mean percentage was 37%. The five items in the upper half of the priority ratings thus were items with a priority of over 37%. These are shown in Table 2.

Table 1 General challenges for clinical mental health research

| Challenges   | Rating |
|--|--------|
| 1. Development of new treatment interventions (pharmacological, brain-related [eg, deep brain stimulation], psychotherapeutic, systemic, psychosocial, e-Health/m-Health approaches and virtual reality/gamification or a combination of these, for mental disorders | 3.6    |
| 2. Exploring the mechanisms of diseases  | 3.5    |
| 3. Evaluation of treatment effects   | 3.4    |
| 4. Proof of concept clinical trials for innovative treatments  | 3.3    |
| 5. Role of comorbidity between mental disorders and somatic conditions for diagnoses, treatment decisions, and treatment and patient-related outcomes  | 3.3    |

Notes: Number of respondents: 87. Complete rating table experts first round: 23 items. Range 2.6–3.6.

### Advances

According to the experts, the challenge with the highest priority was: “to increase research on new intervention approaches in order to gain more insight into their working mechanisms and to successfully develop effective new interventions.”

According to the experts, advances required to meet this challenge were: research on strategies in order to foster adherence to treatments or interventions; exploration of mediators and moderators of outcome; assessment of differential treatment effects, ie, if specific approaches are more effective for specific subgroups; development of e-Health/m-Health approaches and assessment of the level of human contact needed to motivate individuals toward sustained use of e-Health/m-Health treatments; and incorporation of patient perspectives in treatment.

The challenge rated as second in terms of priority was: “to conduct research in order to reach a wider understanding of different mechanisms (eg, psychological mechanisms, biological mechanisms, brain mechanisms, molecular mechanisms and environmental interactions) that may underlie diseases.”

Table 2 Methodological challenges for clinical mental health research

| Challenges  | Rating |
|---|--------|
| 1. Design of psychotherapeutic intervention studies     | 73%    |
| 2. Design of patient preference studies                 | 51%    |
| 3. Design of psychopharmacological intervention studies | 46%    |
| 4. Use of placebos in clinical research                 | 41%    |
| 5. Performing cohort studies in clinical populations    | 41%    |

Notes: Number of respondents: 84. Complete methodological rating table experts first round: 11 items. Range 2%–73%.

The challenge rated third in priority was: “to conduct research on different approaches to evaluate treatment effects.” According to the experts, advances required to meet this challenge were of a more methodological nature, including standardization of psychotherapeutic treatment studies, equivalence trials, research on side effects of treatments, alternative and/or nonrandomized designs, and improved reliability and validity of outcome measures.

The challenge rated fourth in priority was: “to perform proof of concept clinical trials for innovative treatments.” Experts indicated that advances of an infrastructural and methodological nature were required to meet this challenge and establish (European) research networks to coordinate and facilitate clinical research, and to identify or develop standard definitions and guidelines to increase the understanding of the term “proof of concept”.

The experts were asked to indicate if specific patient groups, age groups, or disorders should be targeted, but in general there was no inclination toward a specific group, except the one defined in the fifth challenge. Experts identified the fifth challenge as the need for specific attention focused on comorbidity between somatic and mental disorders. The advances suggested by the experts to address this challenge were to develop and increase research in order to better understand the mechanisms of comorbidity between mental disorders and somatic conditions, including diagnostic strategies and interventions that target such comorbidity.

## Policies

Finally, the three most prioritized policies indicated by the experts are shown in Table 3. These were an overall need for funding of randomized clinical trials in the field of clinical mental health research, the importance of Horizon 2020 in this respect, and adaption of outcome measures for research according to patients’ expectations.

## Discussion

### Study limitations

The main limitation of this study is that it was based on a survey that was sent to 313 experts, of whom only 89 collaborated. Because of limitations imposed by spam filters in operation at universities, we can only be sure that 105 experts actually received the invitation for the survey, given that they accessed the system in order to indicate if they wished to collaborate, despite all efforts indicated earlier to contact experts in various ways. Thus, the response rate was 28%, which is within the range that can be expected for an email survey.

**Table 3** Top three policies needed to meet the gaps in clinical research in Europe

|  |      |
|--|------|
| 1. Funding for independent (multinational) clinical trials in Horizon 2020     | 2.77 |
| 2. National funding for independent clinical trials                            | 2.68 |
| 3. Adoption of common outcome measures in line with the patients’ expectations | 2.48 |

**Notes:** Number of respondents: 87. Complete rating table experts first round: 10 items. Range 2.2–2.77.

## Study strengths

There were also some strengths in this survey. First, generalizability of the results may be good because the participating experts were representative of the target sample of all experts in Europe. Of all respondents, 79% were male, most were aged older than 50 years, and most were professors from a variety of European universities and university hospitals. Nearly all EU-28 countries were represented. Second, the number of experts may be considered high compared with most other studies describing expert opinions on research. Third, we surveyed a priori challenges using open-ended questions, providing an opportunity to suggest new areas, while avoiding contamination with the a prior section. Finally, it is also noteworthy that all data extraction was performed independently in duplicate by two researchers, and the findings were discussed with experts during the scientific workshop.

## Main findings: need for new interventions

Three of the five priority items highlighted an overwhelming need for development and scientific evaluation of new interventions for mental disorders in the field of clinical mental health research. This type of research may be referred to as “experimental medicine”, regardless of whether the mechanism under investigation is biological or psychological. The interventions regarded to have potential range from biologically oriented interventions such as pharmacological interventions and deep brain stimulation to psychotherapeutic, systemic, and social interventions. In addition, experts see potential for various kinds of treatments that use digital devices and/or information computer technology support, such as decision aids, m-Health, e-Health, and serious gaming. e-Health and m-Health interventions are mentioned by the experts, with the specification that research is required to improve sustained use of these interventions by patients.<sup>12</sup> An important issue is the risk of health care provider withdrawal and patient disengagement found in e-Health research<sup>25–30</sup> and the need to examine e-Health and m-Health as tools to augment the process of face-to-face

care, rather than replace it.<sup>31</sup> In Europe, industry is involved in information computer technology developments in the field of e-Health as well as m-Health, and this may provide Europe with opportunities to collaborate in this field in a precompetitive environment, combining efforts of companies and research in the context of Horizon 2020.

In the same vein, the creation of a precompetitive combined research and industry environment may be needed in the context of Horizon 2020, given that many pharmaceutical companies have withdrawn from central nervous system research. Furthermore, new developments in neuroscience may open up opportunities for innovation in the future. This raises the question of to what degree governmental and independent funding will be able to develop new medications, possibly in collaboration with the pharmaceutical industry on an independent basis. A shift may be required in order to identify and test novel molecules in non-industry settings. Another challenge in the area of pharmacological interventions concerns the development of effective and safe algorithms for prescription of medication. For example, combinations of antipsychotic medications have rarely been tested, given that this type of research is rarely facilitated by the pharmaceutical industry, and is not routinely funded by the government either, whereas such research performed by independent clinical researchers may yield clinically relevant findings. For the same reason, head-to-head trials are also scarce, leaving many open questions on the relative benefit–risk of medicines for mental disorders.<sup>32</sup>

Another focus for research in this area concerns the study of possibly synergistic effects of combined psychopharmacological and psychotherapeutic interventions, given that the impact of pharmacological compounds is thought to be contingent on experience-based alterations in the brain and mental functioning in many ways. A more synergistic approach may also help to inform about the moderators, mediators, or even mechanisms of behavior and behavioral change.<sup>10</sup>

Furthermore, the emphasis on European growth in Horizon 2020 may support the indication by the experts of the importance of research into interventions aimed at return to work in sick-listed employees with a mental disorder; governmental organizations, trade unions, medical insurance companies, and social insurance companies may be relevant stakeholders in this effort.

## Methodological advances needed for evaluation of treatment effects

A distinct need for innovation was identified, and in connection with this need, experts indicated that methodological

advances are essential for intervention research. A need to develop methodology and design factors for proof-of-concept trials evaluating novel treatments was identified, eg, relatively small trials exploring the possible effect of a new intervention by assessment of intermediary outcomes.

Methodological issues are considered a priority in relation to the need for new psychotherapeutic interventions as well. In psychotherapeutic intervention studies, blinding problems are an issue. Studies are required to explore possibilities to work with placebo conditions in psychotherapeutic trials, and to explore the neurobiological underpinnings of placebo effects in psychotherapeutic interventions.<sup>33</sup> Also, equivalence studies are needed as an alternative. Standardization of psychotherapy in research is an important issue, particularly in terms of replicability and internal integrity, as well as fidelity to treatment protocols. This problem, if properly addressed, could be translated to clinical practice by pragmatic trials exploring treatment adherence of patients and therapists alike. Also, in randomized clinical trials and meta-analytic reviews in clinical mental health research, particular attention should be paid to diminishing potential bias and resultant loss of external validity.<sup>34</sup> It should also be taken into account that methodological advances are needed to translate findings derived from often well prepared and well conducted clinical research into clinical practice, ie, by mixed-methods designs combining pragmatic randomized clinical trials with qualitative research evaluating conditions facilitating implementation of effective interventions.

## Patient-oriented clinical intervention research

Experts in clinical research indicated a need for patient-centered approaches. Among the advances suggested, the importance of tailoring treatments to specific patient profiles or diagnostic subgroups was mentioned as a high priority,<sup>35</sup> as well as the importance of patient-oriented clinical mental health research based on outcomes that are clinically relevant to patients. Outcomes of clinical mental health research can be specified at the level of the main symptom, global treatment response, remission, or occurrence of relapse, but also at the level of quality of life and functioning, eg, in terms of work absenteeism in patients who are on sick leave. Also important as an outcome is societal participation other than work and the concept of personal recovery, reflecting the higher-order process of adaptation and self-management. Clinical mental health research should be sensitive to patient perspectives, and take into account patient preference in the design, experimental therapy, execution, and outcome

specification of randomized clinical trials, and address adherence of doctors and therapists as well as that of patients with treatment protocols as process or outcome measures. Research may also take the patient perspective into account with use of shared decision-making methods. Both pilot studies<sup>36</sup> and randomized clinical trials using such treatment models and patient preference designs<sup>37</sup> have been performed in Europe with promising results.<sup>38</sup> Clinical research also encompasses the introduction of methodology to assess patient stratification in order to account for and target specific subgroups based on etiology and/or treatment sensitivity, such as in the application of risk profiles. Both efficacy and pragmatic randomized clinical trials are required in order to establish actual effectiveness in clinical practice, as well as cost-effectiveness.

## Concept and mechanisms of disease and somatic-psychiatric comorbidity

Among the five priorities identified by the experts, the first was the development and evaluation of new interventions, as described above. The other main emphasis, embedded in two of the five main challenges identified by the experts, was on what may be pertaining to current concepts of disease in psychiatry, particularly in terms of diagnosis and underlying mechanisms, as well as underlying mechanisms relevant for treatment, and the relationship between somatic and mental disorders.<sup>13</sup> These were seen as areas for priority in clinical mental health research. There is wide consensus that diagnosis and classification in psychiatry, reflecting our current concepts of disease, is an area in need of improvement. Research in this area should result in the introduction of a system of functional diagnosis in psychiatry, ie, a system of diagnosis that is rich in information on the main functions that therapeutic interventions attempt to remediate.<sup>38</sup> Insight into underlying mechanisms of etiology and particularly treatment are required to develop a system of functional diagnosis.<sup>24</sup>

Somatic-psychiatric comorbidity is frequent and associated with increased mortality.<sup>13</sup> Management of these combined conditions is intrinsically difficult due to diagnostic, treatment-related,<sup>39</sup> and organizational difficulties,<sup>40</sup> and there is an urgent need for the development and scientific evaluation of new treatment modalities in this field, using both mental and somatic outcomes such as mortality and taking into account this diversity. From the perspective of the clinical research experts, research should address diagnostic and treatment complexities in somatic-psychiatric comorbidity, with a focus on novel diagnostic and treatment algorithms designed to support medical decision-making. This need is

closely linked to the other advances needed in terms of our understanding of the mechanisms of disease in clinical mental health research. This brings us to a main problem indicated by the experts.

## Subjectivity gap

Throughout the survey, experts indicated in different ways that there is little connection between much of the research in neuroscience, basic research, and imaging studies in psychiatry, and applied research in clinical practice, ie, both in clinical trials and in patients' experience of the signs and symptoms of their mental disorders, and how these are approached, interpreted, and treated by professionals. Experts identified this as a major problem in mental health research. This problem may be referred to as the "subjectivity gap: the genotyping, imaging or other preclinical studies do not provide input regarding subjective experience. Similarly, they do not relate to diagnostic criteria, and the clinical practice of psychiatry".

It has been noted that preclinical research to date has not yielded reliable diagnostic markers or markers for patient stratification in clinical practice.<sup>41</sup> There is a need for clinical research addressing more precise and more patient-centered diagnostic assessments and patient-tailored interventions, which may lead to so-called stratified medicine.<sup>35</sup> There is also a potential for novel, reliable, and specific biomarkers as well as novel clinical markers that inform diagnosis of mental disorder. There is a need for intensive time-sampling process-related clinical assessments with potential to model symptom level or behavioral level change in a dynamic system of mental experience. Clinical process assessments may be combined with brain-related parameters for the purposes of diagnosis and prediction of treatment response. A combined focus on biological markers and the mental experience of patients may bridge the subjectivity gap and enrich research in mental health.

Some of the methodological advances recommended by the experts may be related to this underlying conceptual problem. The assumption that neurobiological processes represent causes of mental disorders cannot be validated by research;<sup>8</sup> the only relationship that may exist may be a parallel process of changes in social, mental, and neurobiological processes that can be induced by social, psychotherapeutic, and pharmacological interventions.<sup>8</sup> Under that assumption, research is required that enables exploration of these perspectives in a synergistic and nonhierarchical fashion. This would enable researchers to operationalize the working mechanism

of placebo as well as active conditions in psychotherapeutic interventions.<sup>16,42</sup>

If a link could be made between brain-oriented research and clinical mental health research, there should be no hierarchy between neurobiological, pharmacological, psychotherapeutic, and social paradigms in patient-related clinical research. Such an effort would require multidisciplinary teams that connect basic researchers, clinical researchers, and conceptual philosophers, as well as patients with mental disorders, providing the researchers with insights in specific needs as part of a translational effort. Ultimately, this may yield novel concepts of mental disorder. If this challenge is taken seriously by Europe, funding and support of clinical research networks working together with basic scientists in a translational manner is required. Given the predictions regarding the health burden of mental disorders,<sup>22</sup> implementation of such networks at the European level would be productive.

The European clinical research priorities presented in this paper add to the Grand Challenges in Global Mental Health Initiative, which identified global mental health research priorities in the next ten years.<sup>23</sup> The initiative lists top global mental health challenges, ranked by disease-burden reduction, impact on equity, immediacy of impact, and feasibility. In parallel with the ROAMER findings, the Global Mental Health Initiative rank list is also topped by research topics related to improving treatments, eg, on integration of mental health service provision in primary health care and improving children's access to evidence-based mental health care. Although methodological differences between the European and the global priority setting procedures preclude any firm comparative conclusions, it seems that European experts are more preoccupied with developing research methodology, such as classification, standardization, and promotion of proof-of-concept studies. Also, anecdotal evidence suggests that randomized clinical trials in the field of behavioral research are trailing behind in Europe in comparison with other countries, such as the USA. This type of clinical research, and the specific methodological attention required for innovation, eg, proof-of-concept trials, evaluation trials, pragmatic trials, and patient preference trials, tends to be overlooked and underfunded. Clinical mental health research in mental disorders should be brought more into line with other more medically oriented research. The difference between European and global priorities indicates that specific research needs exist in the European context and underlines the need for a specific European research agenda for mental health. Nevertheless, the fact that European Union mental

health experts are putting together a Mental Health Horizon 2020 agenda for enhancing the well-being and happiness of people in the European Union in particular and the world at large, by providing evidence-based, better quality interventions for people suffering from mental disorders, may directly or indirectly provide other nations, including low-income, middle-income, and high-income countries, throughout the world with the opportunity to benefit from this planning and development framework. In the following second stage of the expert survey, we expect to focus further on how the experts expect to achieve the priorities and to analyze on which approaches consensus may be found.

The European Union research funding programs have been criticized for being too focused on biomedical research in the area of health, thus disregarding important translational research, such as implementation research, health systems and health policy research, and public health research.<sup>43,44</sup> Indeed, in 2011, only 4% of the €642 million cooperation program for health research in 2011 was allocated to these fields.<sup>45</sup> Our results indicate that randomized clinical trials in the field of mental disorders and translational and implementation research need a more visible position in the Horizon 2020 program than in previous European Union health research activities.

## Conclusion

Innovations in clinical mental health research should bridge the gap between mechanisms underlying novel therapeutic interventions and patient experience of mental disorder and, if present, somatic comorbidity. Development of new interventions is needed, as well as studies evaluating these interventions, and pragmatic trials evaluating how to disseminate and translate basic research findings for application in clinical practice. The methodological advances needed for this purpose, as mentioned by the experts, should be developed whilst taking into account the need for enhanced conceptualization and research operationalization. The mechanisms underlying etiology and treatment response in mental disorders should be the subject of research as well as the relationship between somatic and mental comorbidity, with the purpose of translating this knowledge into clinical intervention research for mental disorders. Clinical mental health research is relatively underfunded and should receive specific attention in Horizon 2020 funding programs.

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## Author contributions

This research is published on behalf of the ROAMER consortium. The Clinical Research Task Force was led by CMFC. CMFC, JvO, and SK designed the survey. JvO provided input for the first part of the survey. SK and CMFC devised the predefined challenges in the second part of the survey, and DL and JvO provided input for this part as well.

SK and IE analyzed the survey data in duplicate. CMFC presented the data at the Scientific Workshop. CMFC wrote the paper, and JvO, EV, SK, GS, H-UW, JMH, SWL, CO-T, DL, IE and KW contributed and approved the final version.

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## Supplementary material

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