# Factors Affecting Implementation of Digital Health Interventions for People with Psychosis or Bipolar Disorder and/or Their Family and Friends: A Systematic Review

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#### Summary

Digital health interventions present an important opportunity to improve healthcare for people affected by psychosis or bipolar disorder, but despite their potential there have been widespread difficulties in integrating and implementing them into clinical settings. This review aims to identify factors affecting implementation of digital health interventions for people affected by psychosis or bipolar disorder. We searched 7 databases and synthesised data from 26 studies using the Consolidated Framework for Implementation Research. Attitudes and beliefs about interventions were crucial factors for both staff and service users, with negative attitudes and scepticism resulting in a lack of motivation to engage with or complete interventions. The complexity of the interventions was a barrier for people with psychiatric symptoms, lower premorbid IQ, or lower IT skills. The accessibility and adaptability of interventions were key facilitators but lack of resources, finances and staff time were barriers to implementation. Interventions need to be user-friendly and adaptable to the needs and capabilities of people with psychosis or bipolar disorder and the staff who support their implementation. Service users and staff should co-facilitate the process of developing and implementing the interventions.

## **Background**

Good-quality treatment and management for people affected by psychosis and bipolar disorder is complex and costly. <sup>1, 2</sup> Digital health interventions (henceforth referred to as digital interventions) present an important opportunity to improve healthcare for this population. They encompass web interventions, mobile Health (m-Health) and telehealth and provide support and treatment for health problems via a platform or device – for example, a mobile application (app) or a website. <sup>3</sup> With mobile device ownership increasing amongst those with psychosis and the majority indicating that they are in favour of using m-Health for self-management, <sup>4</sup> investment and interest in digital interventions is growing. Although still in its infancy emerging data suggests that digital interventions may be as effective as more traditional, non–technological self-help interventions <sup>5, 6</sup> at improving symptom monitoring, <sup>7</sup> medication management, <sup>8</sup> and access to information and support. <sup>9</sup>

Mental health services are often designed to be family and friends orientated and digital interventions could play an important role by providing support digitally where practical issues may impede access to conventional psychosocial interventions. <sup>10, 11</sup> To date trials have shown that online psychoeducation is useful and acceptable to relatives of those with bipolar disorder <sup>12</sup> and schizophrenia. <sup>9</sup>

Despite their potential, there have been widespread difficulties in integrating and implementing digital interventions into real-world clinical settings, an indication of the evidence-practice gap. <sup>13, 14</sup> For example, despite evidence suggesting that it can be effective in treating depression and anxiety, <sup>15, 16</sup> computerised CBT is not yet widely used in clinical practice, <sup>17</sup> and when it is 'prescribed', high drop-out rates have been reported. <sup>18</sup> There is a clear need for implementation research to drive our understanding of how to promote uptake and integration of evidence-based digital interventions.

A meta-review by Ross et al. on implementation of e-health found that key strategies for successful implementation included implementation planning, training and education of staff, and continuous evaluation and monitoring. <sup>19</sup> Other factors identified related to the characteristics of the intervention – its cost, complexity and adaptability to the local organisation, the individual characteristics of the staff, and financial and legislative support for the digital interventions. A later systematic review concluded that failure of e-health interventions across all health conditions was related to the high cost of the interventions, high staff turnover and the additional workload of the intervention for the staff. Another systematic review found that three key determinants of successful implementation for the routine care of common mood disorders are: on an individual level, the acceptance of the digital intervention by service users and professionals, and its appropriateness in addressing the individual's mental health problems; and at the organisational level, the availability and reliability of required technologies. <sup>20</sup> It is not clear to what extent the findings of these reviews will apply to those with serious mental health conditions and this is the first systematic review of factors affecting the implementation of digital interventions specifically for people with psychosis or bipolar disorder, and their family or friends.

Objectives were:

To identify the existing literature on the implementation of digital interventions for people affected by psychosis or bipolar disorder.

To identify, synthesise and interpret key factors affecting the implementation of digital interventions for people affected by psychosis or bipolar disorder.

To provide recommendations for future implementation of digital interventions for people affected by psychosis or bipolar disorder.

# Methods

Design

This systematic review follows Cochrane guidance on conducting reviews <sup>21</sup> and the Preferred Reporting Items for Systematic Review and Meta-analysis (PRISMA) guidelines. <sup>22</sup> The eligibility criteria for study inclusion were developed using the PICOS framework (participants, interventions, comparators, outcomes, study design). This review protocol was registered with PROSPERO (2017:CRD42017079447).

## **Inclusion Criteria**

Participants/population

Adult service users with a diagnosis of psychosis or bipolar disorder established using any recognised diagnostic criteria were included together as they are often managed by the same mental health services offering the same complex interventions. Family and/or friends of those service users with psychosis or bipolar disorder who were being supported by any adult mental health services were also included.

*Intervention(s)* 

Digital health interventions are defined as programmes that provide support and treatment to service users or their family/friends for physical and/or mental health problems via a digital platform (for example a website, a computer, or an app). The support provided could be emotional, decisional, and/or behavioural and can be delivered with or without facilitation by staff or peers <sup>3</sup>.

Comparators(s)/Control

A comparator or control was not required.

Outcome(s)

Studies with any data on factors that affect the implementation of specific digital interventions for people with psychosis or bipolar disorder in mental health services were included. This included factors at level of individuals, the organisations, and systems.

Study Design

All studies which collected primary data (including qualitative) with the aim of reporting on factors influencing implementation of a digital intervention for the population described above were included. In line with previous reviews relating to digital health, only papers published after 1 January 1995 were included. <sup>23, 24</sup>

# **Exclusion Criteria**

Intervention(s)

Digital health interventions that were screening or monitoring tools for psychiatrists or health professionals and did not involve service users or family/friends directly using the intervention were excluded. Digital interventions that were not yet in use, even in a research setting were excluded.

Study Design

Abstracts that had been published only in conference proceedings or journals without full text were excluded. Studies where there was no qualitative or quantitative assessment of the relationship between the factors that impact on implementation of the digital intervention and the degree of implementation, or where the factors that impact on implementation were reported only in the discussion section of the paper, were excluded.

Search Strategy, Data Screening and Selection

The search strategy is displayed and flow diagram of study selection are shown in Panel 1 and Figure 1 respectively.

## Data Extraction and Risk of Bias (Quality) Assessment

A data extraction form was designed for this study and piloted on three studies. We chose not to conduct a quality appraisal for the studies included or to use this as a basis for study selection because the literature in this field is in its infancy; we wanted to be inclusive and we were not examining effect sizes.

## **Data Synthesis**

A framework analysis method <sup>25</sup> using the Consolidated Framework for Implementation Research (CIFR) was used to guide the synthesis of the data by lead author (GA) using NVivo11. <sup>26</sup> The CFIR is an overarching framework which has been developed to encompass all available implementation theories and provides a systematic way of identifying the factors that have been associated with implementation of interventions into practice. The framework is composed of five major constructs: Intervention characteristics (e.g. relative advantage, complexity, cost)

Outer setting (e.g. needs of patient group, external policies and incentives)

Inner setting (e.g. networks, implementation climate, available resources)

Characteristics of individuals involved in implementation. This includes actions, behaviours and attitudes of staff and service users. (e.g. knowledge/belief about the intervention, self-efficacy, individual stage of change)

Implementation process, which refers to strategies or methods that could influence implementation (e.g planning, engaging, reflecting). In the CFIR this process includes factors that impact on engagement at the level of the individual user, as well staff and organisational engagement, and so we have included these factors in this review.

To enhance validity, researchers (JR and TM) independently verified a 15% subsample of the coding. A narrative synthesis was then undertaken of the factors affecting implementation outcomes. The findings from each construct of the CFIR were discussed and reviewed with the wider research team throughout the analysis; any areas of disagreement were discussed and the coding manual refined until there was complete agreement between reviewers.

## **Analysis of Subgroups or Subsets**

We systematically explored variations between different populations in the important implementation factors, particularly service users with psychosis compared to bipolar disorder, service users compared to staff, and amongst the various types of digital intervention.<sup>27</sup>

## Results

#### **Identification of relevant studies**

Searches of the seven electronic databases identified 3359 unique citations (see Figure 1). Of these, 3026 were excluded after screening of titles and abstract. Of the 333 remaining, 26 studies met the inclusion criteria which were all from peer reviewed literature.

## Description of the studies included

The studies identified were published between 1995 and 2017, with seventeen of them being published between 2016 and 2017.<sup>28-44</sup> The only study published prior to 2007 involved a telehealth digital intervention. <sup>45</sup> Most of the studies used mixed methods, <sup>28, 29, 31, 32, 34, 35, 37-50</sup> four used quantitative methods <sup>30, 33, 36, 51</sup> and two studies used qualitative methodology. <sup>52, 53</sup> The majority of the studies were feasibility and acceptability trials (42%), <sup>29, 35, 36, 38, 40, 42-44, 50, 53</sup> eight were designed to look specifically at implementation (31%), <sup>28, 30, 32, 45-47, 49, 52</sup> five were pilot studies (19%), <sup>31, 39, 41, 48, 51</sup> and two were RCTs (8%).<sup>33, 34</sup> Seven of the studies included participants with schizophreniform disorders (27%), <sup>29, 30, 37, 38, 43, 44, 51</sup> seven those with bipolar disorder (27%), <sup>28, 33, 36, 40, 41, 49, 53</sup> and the

remaining were for both illnesses (46%). <sup>31, 32, 34, 35, 45-48, 50, 52</sup> None of the digital interventions targeted family or friends and most of the digital interventions (78%) utilised direct support from staff or peers in their delivery. Two of the studies used an implementation plan <sup>32, 52</sup> and none reported using implementation theory. All the papers were written in English. Full details of the included studies can be found in Table 1.

# **Factors that influence implementation**

A narrative description of the CFIR constructs is presented in the text below. There was no data that could not be coded to one of the main CFIR constructs, and findings were consistent across different healthcare settings and types of digital intervention. Quantitative data is displayed in Table 2 and a list of the CFIR constructs identified in each study is displayed in the Supplementary material.

## **INTERVENTION CHARACTERISTICS**

## **Relative Advantage**

Relative advantage refers to an individual's perceptions of the advantage of implementing the digital intervention versus the alternative or current solution. <sup>26</sup> The main relative advantage reported of digital interventions was their accessibility to service users over non-technological approaches.

Benefits of this included having interventions immediately available during crisis <sup>29</sup> and the reassurance of having remote support perceived to be akin to talking to a doctor on a regular basis.

<sup>35</sup> <sup>38</sup> Users also spoke positively about being able to access the digital interventions independently, in their own time, in their own home, <sup>31</sup> and sharing them with family/friends. <sup>44, 53</sup> Staff spoke of a telehealth intervention being particularly suited to supporting those who had a need or incentive to stay at home. <sup>50</sup>

Digital interventions were also reported to aid communication and help build relationships between users and their medical team. <sup>32, 41, 44, 48</sup> In a shared decision-making intervention for psychotropic

medication, it was reported that users were able to disclose information that they felt uncomfortable or unable to tell a clinician directly, for example, about drug and alcohol relapse, pregnancy plans, wanting "hip-hop abs", and general concerns about using medication. <sup>48</sup> A web-based digital intervention that was used both independently and then with a facilitator was reported to help guide discussions; "without the website we wouldn't have had nearly as much to talk about". <sup>44</sup> However, others spoke of digital interventions without any human support feeling impersonal, <sup>38</sup>, <sup>40</sup> saying that more emphasis should be "not on automation but a real life man with deep psychological problems". <sup>38</sup> Some users echoed this saying they preferred face-to-face communication <sup>44</sup> and indicated that the younger generation were more accepting of digital interventions. <sup>44,53</sup>

A mindfulness app was found to be a welcome change from medication or face-to-face interactions in an inpatient unit, helping to relieve boredom and giving users a positive activity to focus on. <sup>42</sup> The privacy and anonymity of online digital interventions was reported as an advantage by some, <sup>53</sup> but fears about cybersecurity were also a barrier, with one person declining to take part in a study due to privacy concerns <sup>48</sup> and other users worried about privacy when using a digital intervention on a public computer. <sup>53</sup>

#### Adaptability

A key finding was the need for services to be able to adapt interventions so that they can work alongside or within existing infrastructures.<sup>32,39</sup> In a shared decision-making intervention, the individual had used an app prior to meeting with the clinician. However the lack of integration of this information from the app into the existing IT system meant that the clinician did not always know this in advance. <sup>39</sup> This lack of interoperability was overcome in another study whereby prompts were incorporated into the existing electronic system to flag to staff which individuals were completing the intervention. <sup>32</sup>

Lack of adaptability meant some users found information in psychoeducational interventions too complex, <sup>47</sup> whilst others felt the level was too simplistic and gave this as a reason for discontinuing. <sup>49,53</sup> Both staff and users commented on the importance of making interventions more patient-centred so that they could be tailored to the specific needs of the individual. <sup>52</sup>

## Cost

Although digital interventions are promoted as long term cost-saving opportunities, in the shorter term cost was considered an important implementation factor across all types of digital interventions, with lack of staff, training, space, and necessary equipment all being attributed to a financial deficit. <sup>40, 45, 47, 50, 52</sup> Only one study completed a formal cost analysis but others reported on removing human facilitation to reduce cost, <sup>40</sup> and the impact of care providers agreeing to absorb the cost of implementation on uptake and sustainability within private healthcare systems. <sup>28</sup>

## Complexity

Many studies reported on a disparity between the IT skills required for the intervention and those possessed by the users and/or staff. <sup>38, 39, 43, 46, 52</sup> This hindered the execution of the intervention, with users completing tasks slowly, requiring extra time with staff, feeling frustrated, and discontinuing the intervention. <sup>37</sup> Higher completion outcomes were shown for smartphone interventions in users with a higher Functional Assessment Short Test score, more years of smartphone usage and higher premorbid verbal IQ. <sup>51</sup>

# **INNER SETTING**

# **Readiness for Implementation**

## **Available Resources**

Lack of a suitable infrastructure to support the delivery of digital interventions was reported as a

major barrier to implementation across several studies. Infrastructure problems included lack of access to computers, printers <sup>46, 52, 53</sup>, space <sup>28, 34, 52, 53</sup>, equipment <sup>28, 47, 52</sup>, or Wi-Fi/internet access. <sup>42, 47, 52, 53</sup> Whilst cost was cited as a factor for this, there was a sense across these studies that there had been a failure in implementation planning across all types of interventions. <sup>32, 34, 47, 52</sup> The availability of staff trained to implement interventions was also limited due to a lack of investment in their training, the high demands of their clinical workload and a rapid staff turnover. <sup>28, 32, 52, 34, 39, 52</sup>

#### INDIVIDUAL CHARACTERISTICS

# **Knowledge and Beliefs**

Attitudes and beliefs about digital interventions were crucial implementation factors for both staff and users. Positive beliefs that the intervention would help management of symptoms, <sup>38, 42</sup> enthusiasm and interest in the intervention, <sup>34, 46, 52</sup> trust in the team delivering the intervention, and the knowledge that it had been developed by other service users <sup>40</sup> were all cited as factors in increasing end user engagement. However, negative attitudes to IT generally, <sup>52</sup> the preference for face-to-face interventions and lack of interest in digital interventions meant that while users may formally complete sessions, these sessions were less successful as they were more interested in browsing other websites, did not interact with staff in sessions, and did not utilise the available peer support. <sup>46</sup>

From a staff perspective, the belief that the software was a well-developed time-saving resource fostered a positive attitude that could in turn motivate users to be more responsive and more engaged in the intervention <sup>32, 39, 42, 52</sup> while scepticism, and negativity were reported as barriers. <sup>32, 34, 45, 52</sup> Some members of staff lacked IT skills and were reluctant to use digital technology in daily clinical practice digital intervention <sup>52</sup> whilst others recognised the importance and necessity for staff engagement from the onset of the process to support the successful implementation .<sup>32, 52</sup>
Facilitators included more information and training regarding the intervention and its expected

benefits, more IT skills training, and tailoring the digital intervention to the needs of the individual service user.<sup>34, 52</sup>

#### **Other Personal Attributes**

Sociodemographic factors were also noted to affect implementation. Female digital intervention users with schizophreniform disorder <sup>30</sup> or bipolar disorder <sup>49</sup> were more likely to engage with interventions than males. White users were found to be more engaged than Hispanic and African-American users in a mobile intervention for those with schizophreniform disorder <sup>30</sup>. In two studies, younger people with psychosis or bipolar disorder (less than 30 years of age) were less likely to engage and complete the digital intervention than those who were older. <sup>30, 49</sup> In a study with a mixed population, those with a vocational education had more successful education sessions than those without. <sup>46</sup> Yet in other studies for those with bipolar disorder only there were no statistically significant correlations between engagement with digital intervention and age or education level. <sup>33, 36</sup>

Other patient factors related to the interplay between their psychiatric illness and the interventions. In an inpatient setting those with more serious mental symptoms took longer completing sessions <sup>46</sup>, <sup>52</sup>, and people with schizophrenia had fewer successful sessions than those with other mental health diagnoses <sup>46</sup>. In a mHealth study for those with schizophreniform disorder, non-completers were more likely to have severe negative symptoms but with no difference in positive or depressive symptoms. <sup>51</sup> Some participants with bipolar disorder self-reported not adhering or having difficulty engaging with interventions when depressed. However others spoke of being motivated in finding solutions in online programmes when depressed. <sup>49,53</sup> No association was shown between adherence to a mHealth intervention and baseline symptoms of mania or depression for those with bipolar disorder. <sup>33</sup> Users with bipolar disorder also reported a reluctance to complete interventions as they expressed fears it would cause symptom exacerbation or relapse. <sup>49</sup> However this was only reported amongst those with psychosis and even then in a minority of cases with users found to be

## **Process**

#### **Engaging**

Engaging refers to attracting and involving individuals in the implementation process and use of the digital intervention through a combined strategy of education, training, and other similar activities. It includes both strategies to promote engagement and outcomes related to engagement.<sup>54</sup> For digital interventions that involved staff support, enthusiastic clinicians would engage with the intervention and become familiar and confident with its use. <sup>39</sup> They would often remind service users to complete the intervention, <sup>44, 49</sup> reinforce its importance, and provide regular guidance. <sup>42</sup> Digital intervention users were more likely to complete an intervention if staff were involved 46 and if it was introduced by a staff member who found it useful. <sup>39</sup> Even remote support such as staff support online and infrequent telephone calls were found to be key in staying in the study and using the digital intervention.<sup>40</sup> Peer support offered by other service users was also found to be an effective method of improving engagement <sup>47, 49</sup> and achieving higher adherence rates compared with unsupported interventions <sup>49</sup> and staff who found the interventions fun and/or beneficial tended to use the digital intervention more. 31, 34, 42 Participants who did not engage spoke of feeling unwell, worried that the digital intervention would exacerbate symptoms, or finding the process tedious. 49 A greater number of lifetime psychiatric hospital admissions was associated with an increased likelihood of discontinuing the intervention. <sup>30</sup> The level of engagement with a mobile intervention was also shown to decline over time for all digital intervention users. 30

#### Discussion

# **Principal findings**

This systematic review identified and synthesised factors affecting implementation of digital interventions for people with psychosis or bipolar disorder, and interpreted these findings in the context of CIFR. These findings were consistent across different healthcare settings and digital intervention domains, with some variation of implementation factors between those with bipolar or schizophreniform disorder. Multiple factors were important for implementation in all studies with no single factor identified as the key barrier or facilitator. The review did not identify any eligible studies looking at implementation factors of digital interventions for family or friends of people with bipolar or psychotic disorder highlighting an important gap in the literature. Current research is being conducted which aims to address this issue.<sup>55</sup> The majority of factors for effective implementation of digital interventions were centred at the level of the individual or the intervention. Digital health intervention users were more likely to complete an intervention if facilitated by staff or peer support, and if a staff member who found it useful introduced it. The complexity of the digital intervention was a barrier for people with psychiatric symptoms, lower premorbid IQ, or lower IT skills, as these often resulted in difficulty concentrating, engaging, and completing interventions. Female gender and being white were associated with more successful completion of interventions. People with bipolar disorder spoke of concerns on how digital interventions could impact their mental health, although the literature found that it was a minority of people with psychosis who became paranoid or suffered with symptom exacerbation. With regards to the digital interventions, their accessibility and adaptability were key facilitators but their cost was a barrier. Although there was evidence to support the case for digital interventions making long-term savings, the up-front costs for developing interventions, and the ongoing delivery costs are likely to be important factors in services transitioning to more digital services. 50 There was a paucity of evidence in our review regarding organisational and process factors that affect implementation for digital interventions. We would recommend that future research examines the effects of organisational factors in the inner and outer setting and ensure sufficient financial support is in place to support implementation. A summary of recommendations for implementation of digital interventions for people with psychosis or bipolar disorder is presented in Panel 2.

# Comparison with other work

The results of this review are comparable to other systematic reviews on e-health interventions examining implementation across a range of healthcare systems. <sup>19 56 20</sup> All of these reviews found that the best conditions for successful implementation are when the digital intervention is user-friendly, interoperable with existing systems, and adaptable to the local environment and the user. Additionally, they all cited cost as a key factor – indeed, one review found that it was the most frequently mentioned issue when interventions failed.<sup>20</sup> Other common barriers amongst all studies were staff members' lack of IT skills, negative attitudes toward digital interventions, and general resistance to change. Granja et al. also cited similar barriers of high staff turnover, undermining of face-to-face communication and high workload, with staff reporting that digital interventions were both time and resource intensive. <sup>20</sup>

Outer setting factors such as external policies and incentives were previously identified as important for the implementation of digital interventions, in addition to factors related to implementation planning. <sup>19</sup> By contrast, our review found a paucity of studies that looked at this aspect of implementation. This lack of reporting, evaluation, and thought around implementation reflects the fact that digital interventions for psychosis or bipolar disorder are not as established as those for physical or common mental health problems.

Our data supports the existing literature on a 'person-based approach' <sup>57</sup> to developing and tailoring the digital intervention to the needs of the individual, for example building in flexibility in the amount of human input required <sup>3</sup>. This is of particular relevance to people with psychosis or bipolar disorder who may have less experience using digital technology and/or a degree of cognitive impairment <sup>58</sup>. Our findings also highlight the necessity for a better understanding of how to tailor digital

interventions to the needs of particular groups, such as Black/Asian/Minority ethnic groups (BAME), males, and/or those with more severe psychiatric symptoms when designing digital interventions. <sup>59</sup>

# Methodological strengths and weaknesses

This is the first systematic review that examines key factors affecting implementation of digital health interventions for people with psychosis or bipolar disorder. The broad search strategy, including seven databases and grey literature, ensures a comprehensive review, but nevertheless it has limitations. Most of the studies identified were preliminary evaluations of the acceptability and feasibility of digital health interventions for this population rather than implementation studies. Further, none of the studies used implementation theory and their findings were retrospectively organised into the CFIR by the authors. There was also a wide variation in the methodology, setting and type of digital interventions, all of which may have impacted the implementation, so it remains uncertain whether findings are specific to particular settings or interventions. There was also a lack of consistency amongst the definitions of engagement, which limits on the extent to which meaningful comparisons can be drawn across studies. Finally no data were reported on the representativeness of the study samples, which restricts the generalisability of the results to the clinical population. These limitations are characteristic of a research field in its infancy. Future studies should prioritise the following; 1) Establishing clear parameters for what constitutes "effective engagement"<sup>57</sup> in digital health interventions; 2) Use of implementation theory to inform the development and reporting of clear implementation plans; 3) The financial impact of implementation of a new intervention within their respective healthcare systems, 4) Strategic use of qualitative and quantitative approaches to understanding implementation factors 5) Practice based implementation studies 6) The use of electronic health records to make comparisons between the personal attributes of the study and target population.

**Conclusions** 

Most of the implementation research focused on individual level determinants, highlighting a clear

need for better understanding of the contextual and organisational determinants of successful

implementation. Digital interventions need to be user-friendly and adaptable to the needs and

capabilities of this population and the staff who work with them. Our research supports the need for

human facilitation of digital interventions and the importance of including service users, staff, and

implementation champions as early as possible in the implementation process. Although digital

interventions are often promoted as cost saving in the long run, their start-up and delivery costs are

often overlooked, and future studies must consider the importance of reporting cost-analyses. There

is a current gap in the literature of studies reporting implementation of digital interventions for family

and friends, although such studies are currently underway. Despite the identification of a large

number of studies for this review, important questions remain regarding the optimum method of

development and delivery for digital interventions for people with psychosis or bipolar disorder.

**Declarations** 

Ethics approval and consent to participate

Ethical approval is not required

Consent for publication

Not applicable

Availability of data and material

Not applicable

Competing interests

The authors declare that they have no competing interests.

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# Authors' contributions

All authors contributed to the protocol design. GA, TM, VA, JR executed the search strategy and extracted the data. GA wrote the draft of the paper and this was revised and approved by all authors. All authors approved the final manuscript.

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