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1 SYNTHESIS-READY RESEARCH

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4 **Ensuring Prevention Science Research is Synthesis-Ready**
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6 **for Immediate and Lasting Scientific Impact**
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4 **Abstract**

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6 Synthesis of evidence from the totality of relevant research is essential to inform and improve
7 prevention efforts and policy. Given the large and usually heterogeneous evidence available,
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9 reaching a thorough understanding of what works, for whom, and in what contexts, can only be
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11 achieved through a systematic and comprehensive synthesis of evidence. Many barriers impede
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13 comprehensive evidence synthesis, which leads to uncertainty about the generalizability of
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15 intervention effectiveness, including: inaccurate terminology titles/abstracts/keywords
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17 (hampering literature search efforts); ambiguous reporting of study methods (resulting in
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19 inaccurate assessments of study rigor); and poorly reported participant characteristics, outcomes,
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21 and key variables (obstructing the calculation of an overall effect or the examination of effect
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23 modifiers). To address these issues and improve the reach of primary studies through their
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25 inclusion in evidence syntheses, we provide a set of practical guidelines to help prevention
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27 scientists prepare synthesis-ready research. We use a recent mindfulness trial as an empirical
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29 example to ground the discussion and demonstrate ways to ensure: (1) primary studies are
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31 discoverable; (2) the types of data needed for synthesis are present; and (3) these data are readily
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33 synthesizable. We highlight several tools and practices that can aid authors in these efforts, such
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35 as creating a repository for each project to host all study-related data files. We also provide step-
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37 by-step guidance and software suggestions for standardizing data design and public archiving to
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39 facilitate synthesis-ready research.
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4 **Ensuring Prevention Science Research is Synthesis-Ready**
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6 **for Immediate and Lasting Scientific Impact**
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8 Systematic reviews are vital means of summarizing research to inform policy and
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10 practice because they can provide a robust synthesis of available evidence, accounting for risks
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12 of bias in individual studies, and because the volume of primary research being published makes
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14 it difficult to update policy and practice when new evidence becomes available (Gurevitch et al.,
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16 2018; Johnson & Hennessy, 2019; Wilson & Tanner-Smith, 2014).
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20 To conduct a comprehensive evidence synthesis, such as a systematic review and meta-
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22 analysis, primary studies related to the research aim must be identifiable and report relevant
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24 study and outcome data. The goals of evidence synthesis are often quite different than that of a
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26 trial; as a result, trialists may unintentionally omit information that can be crucial for secondary
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28 analysis. Unfortunately, the lack of transparency in the reporting of primary studies often makes
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30 the work of those conducting evidence syntheses—hereafter labeled *evidence synthesists*—
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32 slower and less accurate (Borah et al., 2017; Haddaway & Westgate, 2019; Nakagawa et al.,
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34 2020; Nuijten et al., 2016; Wood et al., 2018). Evidence synthesists often need information about
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36 measured variables aside from the manuscripts’ primary outcome of interest to explore why there
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38 are differences (i.e., statistical heterogeneity) between studies examining the same intervention.
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40 This information is often missing, which leads to uncertainty about the generalizability of
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42 intervention effectiveness across different groups (e.g., race/ethnicity, gender, age). Even when
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44 studies report their statistical data and results in detail, there is often still important information
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46 missing about other factors that require further attention including author correspondence before
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48 they can be accurately synthesized (e.g., description of the intervention, population, or outcome
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50 measures).
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SYNTHESIS-READY RESEARCH

Given the potential impact of their work on human health and behaviors, prevention scientists should be at the forefront of ensuring primary research is transparent, reproducible and furthermore, we argue, synthesis-ready. *Synthesis-ready research* is our term to describe a study (e.g., randomized controlled trial, RCT), its *meta-data* (i.e., descriptive information about the study's data, including protocols, tools, algorithms, so that one could replicate the study), and *data* (information collected while conducting the study) that can be readily and accurately used in evidence syntheses. Data and metadata may be missing from a primary study for many reasons, including article length restrictions, a lack of detailed reporting standards or awareness of the importance of open data, or a desire to retain control of analyses, amongst others.

Resources are available to enable authors to share detailed data and metadata associated with a study; yet, these resources are often not directly connected to scientific journal practices. Some of these options make it much easier to discover, use, and cite authors' research (for example, in evidence syntheses); substantially increasing the impact and legacy of their work. Thus, our aim here is to draw on resources from across disciplines (Grant et al., 2018; Montgomery et al., 2018; Schulz et al., 2010; Wilkinson et al., 2016) to produce a guide to reporting primary research that is fully open/accessible and synthesis-ready. To illustrate the principles of synthesis-ready research, we draw on an empirical example from a RCT examining mindfulness meditation to improve college student well-being.

1. From Primary Study Research to Evidence Synthesis

The past 10 years have produced advances in primary research study¹ conduct and reporting guidelines, which advocate for reporting enough information for research to be transparent and reproducible and provide specific information on how to do so (Aw et al., 2013;

¹ Primary research can be composed from any type of study design, including experimental (such as randomized controlled trials or controlled trials), observational (such as cohort studies), or mixed methods, to name a few.

4 Grant et al., 2018; Schulz et al., 2010). Similarly, recent efforts have focused on improving the
5 degree of FAIRness of primary studies, by ensuring research is **F**indable, **A**ccessible,
6 **I**nteroperable, and **R**eusable (Figure 1; Wilkinson et al., 2016).² By following Open Science
7 (Frankenhuis & Nettle, 2018; Vicente-Saez & Martinez-Fuentes, 2018) recommendations and
8 addressing FAIR principles, prevention scientists can provide synthesis-ready research that
9 improves the translation of research into practice.
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19 Similar to the conduct of primary research, there are best practices for conducting and
20 reporting of evidence syntheses, including the following: problem formulation; systematically
21 identifying and selecting studies for inclusion; coding studies for key features; calculating effect
22 sizes (if synthesizing quantitative data, such as by conducting a meta-analysis); analyzing the
23 data (assess quality and risk of bias, synthesize coded information from studies); interpreting and
24 communicating results; and eventually, updating and re-analyzing data (Online, Figure 1).
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33 **2. Potential Advantages of Synthesis-Ready Research**

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36 Primary research that is synthesis-ready can benefit the entire discipline as well as
37 primary researchers. Synthesis-ready research can increase the transparency, integrity, and
38 reproducibility of research, ultimately leading to improved scientific evidence (Beugelsdijk et al.,
39 2020). Pre-registration and subsequent data sharing practices are expected to reduce the
40 prevalence of post-hoc hypothesis (HARKing; Forstmeier et al., 2017; Kerr, 1998), and
41 falsifying or misrepresenting data in results (Banks et al., 2019; Miyakawa, 2020). Doing so can
42 reduce duplication of effort and introduce findings to the research community sooner, and ensure
43 that all findings (beneficial and adverse) are reported, results that can prevent costly mistakes
44 (Gupta et al., 2015) and accelerate the impact of prevention scientists (Pasquetto et al., 2019).
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58 ² Although FAIR principles primarily refer to enhancing the ability of machines to find and use data, these
59 recommendations also enhance data reuse by individuals. Where appropriate, we have adapted the FAIR
60 components to more directly apply to human-readability efforts for the purposes of this manuscript.
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SYNTHESIS-READY RESEARCH

Primary researchers who make their work synthesis-ready should also benefit from these efforts. Synthesis-ready research is more likely to be identified and used in evidence synthesis (Christensen et al., 2019; Colavizza et al., 2020; Gerstner et al., 2017). For example, a recent study showed that hosting data in a repository resulted in 25% more citations than merely stating data were available by request (Colavizza et al., 2020). Additionally, depending on the organization of the metadata and the data repository used, the dataset may be cited directly, as may other study materials such as the analytical code, further enhancing the profile of the work and those who conducted it (Crosas, 2013).

Because synthesis-ready research is also more identifiable, there are increased opportunities for future collaborations between primary study researchers, other teams, and evidence synthesists (Popkin, 2019), which potentially improves future resource-sharing and reduces costs. Producing synthesis-ready research can also increase the recognition of an individual study team to an international audience. Many funding sources require data sharing of their grantees and necessitate the inclusion of such plans in grant proposals: Those who prepare and deliver grant-funded research findings with synthesis-ready considerations are considered responsive to funders while potentially attaining these other discussed benefits.

Thus, there are likely many benefits to making research synthesis-ready, despite the slow uptake of openly sharing research data in the social sciences. We will now introduce our empirical example (Section 3) and demonstrate the application of best practices for synthesis-ready research (Sections 4 and 5) to streamline this process for primary study researchers.

3. Introduction to Empirical Example

Our empirical example is a RCT ($N=140$ participants; registered in Clinical Trials, [NCT03402009](#)) conducted across two university semesters in the 2018 academic year (Acabchuk

et al, in press). The study evaluated two active treatment conditions to determine what tools best assist university students in developing a personal meditation practice to self-manage symptoms of depression, anxiety, and stress. One group was assigned to the *10% Happier* meditation phone app (labeled the “App Group”; *Ten Percent Happier*, 2020), which provides guided meditations, and the other was assigned to the *10% Happier* meditation phone app in combination with a Muse EEG neurofeedback device (labeled the “Muse Group”; Choose Muse, 2018). The study included a baseline assessment, randomization to one of two groups, an orientation session for both groups, collection of salivary biomarkers, and follow-up assessments on a variety of well-being and behavior outcomes throughout the study (Figure 2).

4. Evidence Synthesis Process Applied to our Empirical Example

Drawing from our empirical example, if evidence synthesists sought to create a systematic review of all types of mindfulness interventions for college students on health-related outcomes (*Problem Formulation*), they would first need to be able to identify all primary research matching their inclusion criteria (*Finding and Selecting Studies*). Clearly delineating the research problem is a foundational step in a review, as it drives the search strategy and ability to accurately identify and synthesize primary study research. Often, evidence synthesists are encouraged to develop research questions that address all the main elements of the studies they are looking to include; many draw on the PICOS framework with its focus on the population(s), intervention(s), comparator(s), outcome(s), and study design(s) elements of a research problem (Stern et al., 2014). Once the relevant literature is identified, evidence synthesists extract data from the included studies (*Code Studies for Relevant Features*) so that the analysis can commence by synthesizing coded data (*Analyze the Systematic Review Database*).

SYNTHESIS-READY RESEARCH

Within this broader process, the types of data and meta-data that need to be reported depend on the task and/or type of evidence synthesis. For example, research methods need to be fully reported to assess risk of bias. If evidence synthesists sought to measure the effectiveness of mindfulness interventions on depression symptoms using a quantitative synthesis, then included primary studies should report an effect size or the statistics necessary to calculate an effect size from their depressive symptom assessment for all participants (e.g., means, standard deviations, and sample sizes for each group). To address relevant potential effect modifiers (e.g., age, year in school, gender, intervention fidelity), any data collected during the primary study on participant characteristics and the study methods (e.g., description of groups, duration of intervention) needs to be transparently reported. Additionally, if the synthesis focuses on participants' perspectives on why interventions are more or less effective, they would need access to any qualitative data collected as part of the study (e.g., interviews, focus groups). Given this variability in the type of questions that could be addressed in a synthesis, it is important for investigators to transparently and comprehensively report a variety of information about their research.³

5. How to Make Research Synthesis-Ready: Steps from Study Design to Completion

For many researchers, data sharing only becomes relevant towards the end of a project, when the analyses are completed and the manuscript is ready for submission. Approaching every step of the project with data sharing in mind is useful and often necessary to ensure that data sharing is possible. It has the added benefit of encouraging better overall project management, including clearer workflows and comprehensive documentation of the analytical process. Best practice in data sharing at each stage of a project life cycle include study registration; transparent

³ Tables 2 and 3 in the appendix present a mapping of critical elements for a study *protocol* using the SPIRIT guidelines (Aw et al., 2013) and for a study *manuscript* using the Consolidated Standards of Reporting Trials for social and psychological interventions (CONSORT-SPI 2018; Grant et al., 2018)) against how study information to be provided based on these guidelines could be used in an evidence synthesis.

1 SYNTHESIS-READY RESEARCH

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4 workflows; meta-data for identifying authors, results data, published article; and well crafted text
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6 to make the reporting easy to find in bibliographic databases (Figure 3).
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8 **Study Design**

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11 Preparing research for sharing can be a resource-intensive process, and so planning and
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13 provisioning for this task is vital to consider when submitting funding applications and
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15 considering funders' reporting requirements. Many funders, including the Wellcome Trust, the
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17 UK Medical Research Council, and the US National Institutes of Health require data sharing
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19 plans as part of grant applications and budget justifications (Gaba et al., 2020; *NIH Data Sharing*
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21 *Policy and Guidance*, 2003; Wellcome Trust Public Health Research Data Forum, 2012).
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26 When conducting research with human participants, planning for data sharing during
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28 study design is essential because it ensures appropriate documentation is prepared. That is, any
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30 potential ethical concerns with data sharing should be addressed in advance during the review of
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32 study materials (i.e., study protocol, advertisements, consent forms) by the governing
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34 Institutional Review Board, which ensures that consent documents for participants include the
35
36 correct language. Then, participants can consent to anonymized data sharing (Ohmann et al.,
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38 2017; Thorogood & Knoppers, 2017).
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43 The study protocol is the foundation of the study, detailing all the processes, procedures
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45 and materials planned for a research project. Best practice is to pre-register a study protocol that
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47 includes primary questions and/or hypotheses, methodology, and planned analyses. With careful
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49 attention to developing a comprehensive protocol using a standard structure, this document can
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51 increase the synthesis-readiness of the research. The information provided in a study protocol
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53 includes important metadata that may not be available in a single published manuscript but that
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55 can be used by evidence synthesists to address a variety of research questions, including using it
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SYNTHESIS-READY RESEARCH

to assess study quality and risk of bias due to selection of reported results or “outcome switching” (Falk Delgado & Falk Delgado, 2017; Kahan & Jairath, 2018). We recommend that trialists review published guidelines for the best tool for the particular study design in question: The EQUATOR network provides an online resource to compare these tools (<https://www.equator-network.org/>). The protocol for our mindfulness trial uses the *Standard Protocol Items: Recommendations for Interventional Trials* (SPIRIT) guidelines (Aw et al., 2013) and is archived in a Zenodo repository (DOI: 10.5281/zenodo.4011716).

Study Conduct

To facilitate data sharing and to distribute the workload across the projects’ lifecycle, transparent and reproducible data management workflows should be employed throughout the research process, including: (1) defining data file contents; (2) clearly describing variable names, definitions, units and formats; (3) implementing consistent data organization and file structure; (4) performing basic quality assurance to ensure that values fall within expected ranges; and (5) providing documentation including the analytical steps taken (crosswalks), data dictionaries (i.e., codebooks), and metadata (Barton et al., 2010; Strasser, 2012; Yenni et al., 2019). Building in these metadata collection steps into the analysis process makes it easier to create items like crosswalks and data dictionaries to accompany shared research.

Preparing for Study Dissemination

The most labor-intensive stage of making data synthesis-ready occurs during preparation for study dissemination as it involves several steps.

Findability and Accessibility. To address the first two components of FAIR, Findable and Accessible, authors should: (1) ensure all authors have a unique permanent identifier such as an ORCID iD (Open Researcher and Contributor ID; 2009) because institutional emails are often

1 SYNTHESIS-READY RESEARCH
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4 impermanent, and include this identifier with manuscript and data submission; (2) include a
5 detailed data availability statement with manuscript submission; (3) assign data and metadata a
6 globally unique and persistent identifier (e.g. a DOI), which ensures long-term discoverability;
7 (4) use available data ‘tags’ in the archiving repository ; (5) use consistent names/usernames
8 across the different journal and archiving platforms; and (6) craft the title and abstract, and select
9 keywords that will optimize the chances of research being identified via the most typical
10 evidence synthesis method of searching for research (i.e., electronic database searches). Open
11 access publishing and/or publishing a preprint of the manuscript will increase the findability of
12 the research; yet, these options may be restricted by available funds and journal policies. We
13 elaborate on some of these points in the sections below.

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Data availability statements. Data availability statements (DAS; also known as “Data
44 access statements” or “Availability of materials” sections) increase data findability. A
45 comprehensive DAS provides information about how and where other researchers can access the
46 study data; it is increasingly a required component when submitting a manuscript for publication
47 (Federer et al., 2018; Graf et al. 2020). The DAS should be as explicit as possible, even if some
48 information that is in the method section of a manuscript is repeated in the DAS (Figure 4).⁴

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Creating titles, abstracts, and keywords to optimize findability. Carefully crafting titles
and abstracts, in addition to choosing appropriate keywords, is essential to help other researchers
find your research. As much as possible given word limits, these should describe the condition,
exposure, and settings of a study to give readers a quick snapshot of the basics of the research
(Grant et al., 2018; Montgomery et al., 2018). These pieces of the submission are often the last to
be created, but are the main pieces of information indexed and displayed in electronic databases

⁴ In some closed-access journals, DAS are treated as article metadata, meaning that they are accessible even if the full article is behind a paywall, ensuring the relevant data are still open access and locatable

4 and are used by evidence synthesists to identify relevant research. As a result of their ability to
5 increase the findability of research, we suggest a data-driven approach to crafting these sections.
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9 The `litsearchr` package for the R programming environment allows users a systematic
10 method to generate a list of words likely to improve the identifiability of the study manuscript
11 (Grames et al., 2019; R Core Team, 2019).
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16 Using the mindfulness trial, we began with a set of keywords we thought likely to capture
17 a set of relevant published articles from which we could draw the most highly used keywords.
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19 We conducted a search using these keywords in PubMed on August 24, 2020 and used
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21 `litsearchr` to systematically generate a list of important terms (Table 1). The results suggest
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23 that several terms could be strategically incorporated in the title, abstract, and keywords to
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25 increase the findability of the trial.
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31 **Interoperability and Reusability.** To address the third and fourth components of FAIR,
32 Interoperable and Reusable, researchers need to attend to licensing, data file formats, and meta-
33 data when preparing their data for sharing.
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38 **Data licenses.** Assigning a license to the data being shared is important to govern how
39 the data can be reused, and more importantly, to help ensure that the study team is credited.⁵ For
40 our empirical example, we have chosen the CC-BY-4.0 license, which allows the reuse of the
41 data provided the original researchers are credited with the creation of the dataset.
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48 **Data file types.** Study data can be shared as machine-readable (e.g., unformatted
49 Excel/CSV files and raw DNA microarray sequences) or human-readable formats (e.g.,
50 formatted PDF tables, figures, and data contained in text such as “There was evidence of an
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57 ⁵ Comparing the full suite of licences available is beyond the scope of this article; online resources such as
58 ChooseALicence (<https://choosealicense.com/non-software/>) and Creative Commons
59 (<https://creativecommons.org/licenses/>) provide detailed descriptions of the range of licences available for data
60 sharing.
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1 SYNTHESIS-READY RESEARCH
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4 association (Odds ratio: 0.91, 95%CI: 0.85-0.96”). While new tools are being developed to
5 extract data automatically from human-readable sources for evidence syntheses (Marshall et al.,
6
7 2020), it is often challenging to import these data into statistical analysis software, reducing
8
9 interoperability and synthesis-readiness. For our mindfulness trial, all data are shared via Excel
10 files. This includes the mindfulness trial’s qualitative data, which were generated from in-person,
11 semi-structured interviews and which were coded to examine adherence and problems with using
12 the apps. To demonstrate synthesis-readiness, the relevant responses for coding are included in
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14 the data file rather than the full interview notes.
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23 **Meta-data.** Providing a README, a plain text file that contains useful information about
24 data or software, can help ensure that data are correctly accessed, interpreted, and reused by
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26 other researchers, including by evidence synthesists. The README for our mindfulness trial
27
28 contains the seven main elements necessary for a comprehensive meta-data file; see Figure 5 for
29
30 a snapshot of these pieces and visit the Zenodo repository for all files: [10.5281/zenodo.4011716](https://zenodo.org/record/4011716).
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35 (1) The README file should include a definition of the primary research aims using the
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37 PICOTS framework or some relevant alternative framework that addresses the main components
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39 of the research (Haynes, 2006; Johnson & Hennessy, 2019; Stern et al., 2014) which will help
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41 evidence synthesists identify and use the research. (2) A short description of all the data files
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43 included in the project repository should be included in this file. (3) Signposts to the detailed
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45 data dictionaries for each data file should be included; these should contain definitions of all
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47 variables, including coded (e.g., “CRP_t2”) and interpretable (e.g., “C-Reactive Protein levels at
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49 2 months post-baseline”) variable names, the values that each variable is allowed to take, and
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51 include missing data indicators and units of measurement. (4) A summary of data processing
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53 steps that were used to produce the final analytic datasets from the raw data files should be
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1 SYNTHESIS-READY RESEARCH

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4 provided. (5) A description of each data file's relationship to other data files in the repository,
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6 and relevant linkage variables, such as participant ID must be included. (6) The README
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8 should have permanent author contact details, including their ORCID. Finally (7), details of the
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10 license, including the full name of the license holder, the year, and where the full text of the
11
12 license can be found should be provided.
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15 **Archiving and sharing research data**

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19 The two primary considerations when sharing research data include what data to share
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21 and where to share it. We provide several potential options within these categories, ordered from
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23 best practice (most likely to be synthesis-ready) to good practice (still synthesis-ready but may
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25 require additional effort to prepare for synthesis).
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29 **Data to share.** Sharing individual participant data, i.e., data on each variable collected
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31 for each participant, affords evidence synthesists a range of advantages. Access to data on all
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33 variables collected, rather than just those used in the primary study's analysis, allows synthesists
34
35 to ensure that an estimate from a primary study is adjusted for a common set of variables when it
36
37 is included in a meta-analysis, even if the published effect estimate for that study was not (Riley
38
39 et al., 2010). Even among individual participant data, different levels of granularity exist. To
40
41 illustrate the distinction in the level of data shared, for our mindfulness trial, we shared the raw
42
43 data exported from the survey instrument, which contains each participants' answer to each
44
45 individual question, and the processed individual participant data, which include scale score
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47 summaries (i.e., the total DASS-21 score, which is comprised of 21 individual questions).
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53 It may not be possible to share each individual participant data point, especially when
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55 participant confidentiality is at risk; for example, when studying a rare disease or among
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57 participants of specialized programs. In these cases, there are several alternative options for
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4 sharing individual participant data. The first is to generate a “synthetic” dataset that mimics the
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6 individual-level data by preserving statistical properties and the relationships between variables
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8 (Quintana, 2020). Software, for example, the `synthpop` R package, is available to help users
9
10 generate and explore the usefulness of synthetic datasets (Quintana, 2020, provides a tutorial on
11
12 using this package). A second option is to remove some individual participant characteristics that
13
14 might give away participants’ identities, such as age, sex, and location of recruitment source, but
15
16 provide the rest of the variables as individual data points. Finally, if it is not possible to share any
17
18 individual participant data, then at the very minimum, summary-level data (e.g., means and
19
20 standard deviations or percentages which describe the distribution of all variables between
21
22 intervention/exposure groups) should be provided for all variables in the dataset, not solely those
23
24 thought by the primary study team to be relevant.
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31 **Data location.** There are several options for sharing research, and a summary of these
32
33 options, including particular advantages and disadvantages of each, is presented in Table 2.
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35 ***Non-affiliated repositories.*** Non-affiliated repositories are commercial or charity
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37 repositories that allow researchers to self-archive, and assign a DOI to, their research data.
38
39 Examples include Dryad, Open Science Framework, and Zenodo (*Dryad, 2020; Open Science*
40
41 *Framework, 2020; Zenodo - Research. Shared., 2020*). For our mindfulness trial, the repository
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43 was created using GitHub and archived using Zenodo, as GitHub deposition is non-permanent
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45 and does not assign a DOI to the uploaded data. Repositories of this type can be embargoed prior
46
47 to publication to prevent “scooping”, and some repositories also provide services to help prevent
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49 scooping. For example projects in the Open Science Framework can generate “anonymous” links
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51 to remove identifying meta-data as part of double-blind peer-review requirements. The main
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4 limitation of these repositories is that there are often conditions on how much data can be stored;
5
6 some charge fees for storage.
7

8
9 ***Institutional repositories.*** An institutional repository is one hosted by an academic
10
11 institution, such as the Harvard Dataverse (*Harvard Dataverse*, 2020). An advantage of affiliated
12
13 repositories is that some provide staff to guide researchers who are new to data sharing.
14

15
16 However, these repositories are substantially less well-known, which may limit the findability of
17
18 data when compared to other options. The terms and conditions of deposition should be reviewed
19
20 to ensure that authors retain data ownership and copyright over the deposited materials.
21
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23
24 ***Supplemental Files.*** A common option for sharing research data is as a supplementary
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26 file to the published manuscript. However, this method has several major limitations. In the first
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28 instance, this approach reduces the findability of the data because datasets shared as
29
30 supplementary material are grouped under the publication's DOI and are not uniquely
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32 identifiable. There is also the potential for supplementary files to become disassociated with their
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34 respective publications, for example, during a website redesign. Data shared in this way may also
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36 not be accessible; that is, if the published article is behind a paywall, then access to the data
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38 attached to it as supplementary files may also be blocked. Sharing data as supplementary files to
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40 an open-access publication should be considered the minimum level of data sharing needed to
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42 make research synthesis-ready.
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48 **6. Potential challenges and future considerations** 49

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51 In this article, we have outlined the benefits of synthesis-ready research and provided
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53 guidelines on how to follow best practice and produce synthesis-ready research. Yet, we
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55 appreciate that there are many perceived and actual challenges to doing so, including costs to
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57 data sharing, lack of incentives, lack of awareness or training, not wanting to “give away” data or
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1 SYNTHESIS-READY RESEARCH

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4 get “scooped” on findings, and the necessity of ensuring participant confidentiality (Evans, 2016;
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6 Tennant et al., 2019; Tenopir et al., 2011, 2015; van Panhuis et al., 2014; Walters, 2020).
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8

9 To address the lack of knowledge and training, we have provided information and
10 workflows here, in addition to signposting to further literature, to help primary researchers plan
11 for the resources needed for making research synthesis-ready even before the project begins.
12
13 Additionally, many funders have recognized the value of data sharing and will provide funds to
14 do so based on investigator budgets which can offset the tangible (fees for sharing on platforms)
15 and intangible (time spent preparing data for sharing) costs of this process.
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23 Researchers have valid concerns about having their research scooped and yet, several
24 measures can help prevent scooping including pre-registering study analysis plans and depositing
25 preprints while awaiting publication, all core practices of open science. An additional solution is
26 to license data at the point of publication or archival (covered in section 5). Finally, some
27 journals have implemented “scoop-protection” policies for research that has been scooped, a
28 system-level solution we hope more journals will implement to address this challenge
29 (TRANsparency in Scholarly Publishing for Open Scholarship Evolution, 2020).
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41 Ensuring that all types of research data are reused appropriately is a warranted concern
42 (Bishop, 2009; Yardley et al., 2014); yet, evidence suggests that individuals reusing data seek to
43 collaborate with the original data creators to harness their extensive knowledge about the data,
44 rather than using it to scoop the data or to disprove the original publication’s findings, resulting
45 in improved and more accurate data reuse and increased opportunities for publication (Pasquetto
46 et al., 2019). As well, providing clearly detailed documentation in the data and metadata files
47 (discussed in Section 5) should reduce inappropriate use of shared data. Finally, we have also
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4 provided several different options for maintaining the confidentiality of participants while
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6 attending to synthesis-readiness (Section 5).
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9 Several advances in computational abilities may help to increase the future of preparing
10 synthesis-ready research. Federated learning or analysis enable data from different studies to be
11 analysed in a combined statistical model, while retaining the confidentiality and privacy
12 requirements of the separate data custodians (Geleijnse et al., 2020). It involves using an iterative
13 process of model building from all available data, while sensitive data is stored in their
14 respective secure institutions. To date, the application of this method has been limited, but it is
15 an appealing future direction for evidence syntheses and primary studies.
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26 **7. Conclusions**

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28 Despite the importance of making research available and synthesis-ready, not all
29 scientific disciplines have embraced data/metadata sharing and transparency at the same rate
30 (Graf et al., 2020; Hardwicke et al., 2020; Sholler et al., 2019; Vasilevsky et al., 2017; Whitlock,
31 2011). In this paper, we argue that if researchers attended to sharing research in a way to make it
32 synthesis-ready, they and the field of prevention science should see a variety of benefits. In
33 addition, we present several methods to reduce, or at least more easily manage, the tasks of data
34 sharing and to mitigate the perceived challenges we detail in this manuscript. Our hope is that we
35 will soon see increased attention to practices that ensure the products of primary studies are
36 directly fed into evidence syntheses. This will reduce the delay between implementing effective
37 primary study approaches and changing practice (Nakagawa et al., 2020), thereby improving the
38 scientific process and products for future generations.
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Findable: identifiable to anyone searching for it; data and metadata and their locations clearly described.

Accessible: data and metadata are retrievable by their identifier (e.g., a digital object identifier, DOI; www.doi.org) and freely obtainable in full without barriers to access (e.g., without needing to register with an external website or contacting study authors).

Interoperable: data and metadata are understandable across humans or machines without the need for specialized tools or translation, use vocabularies that follow FAIR principles, and include qualified references to other data/metadata.

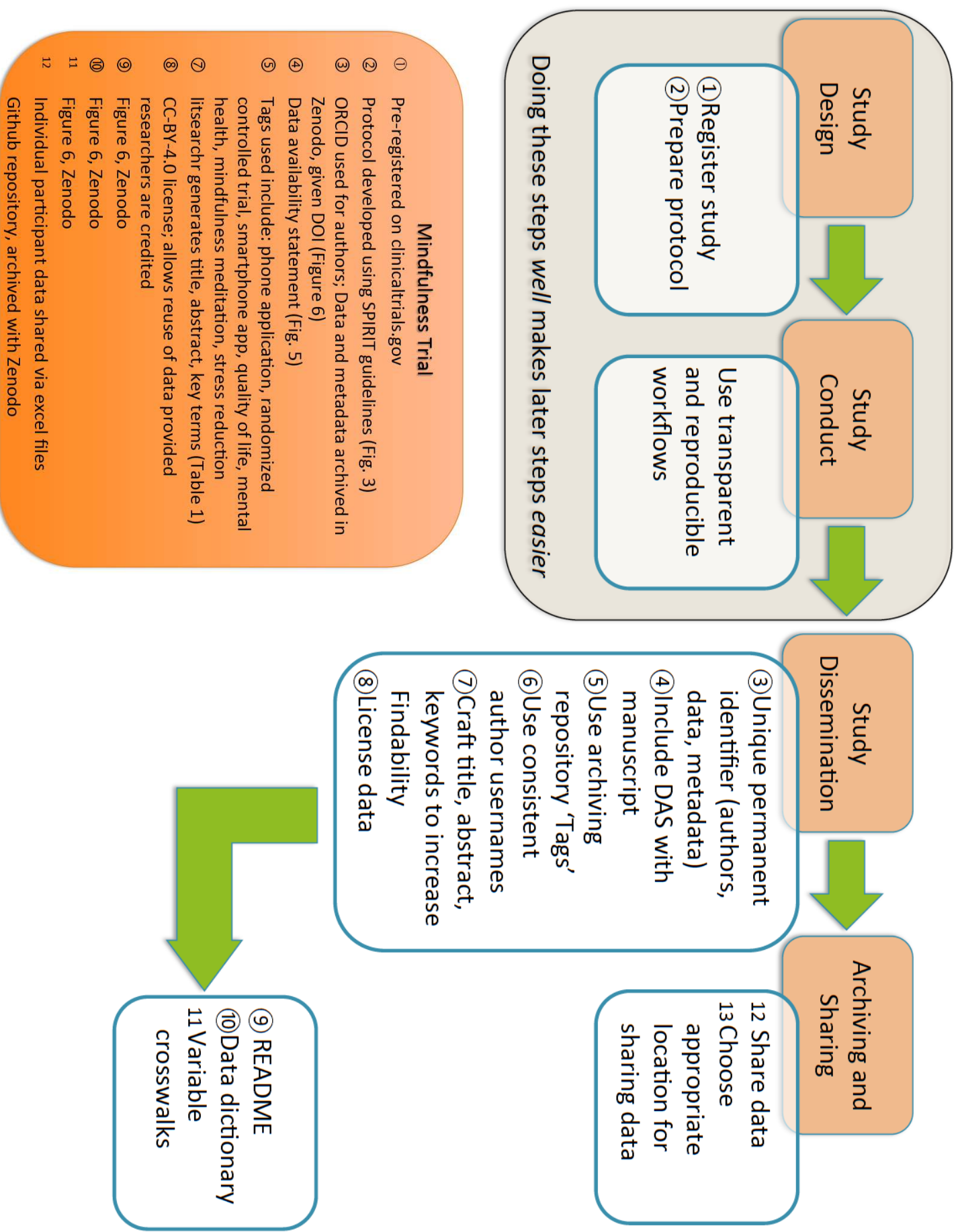
Reusable: degree to which information can be appropriately repurposed (e.g., integrated/built upon, such as in evidence synthesis). Data and metadata have a clear and accessible data usage license (e.g., permissions to reuse), detailed provenance (e.g., records of data origins), and be clearly and richly described in their accompanying materials.

Figure 1. FAIR principles (Wilkinson et al., 2016)

TIMEPOINT**	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			Close-out
	-t ₁	0	1 month	2 months	7 months	13 months
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
1 Hour Orientation	X					
Allocation		X				
INTERVENTIONS:						
<i>App group</i>		→				
<i>Muse group</i>		→				
ASSESSMENTS:						
Demographics, medical history, motivation	X					
Time calm (%) and bird scores during meditation (5 minutes) ^a		X	X			
Salivary biomarkers	X (n = 20)		X (n = 20)			
Meditation tool use; adverse experiences (every 48 hours)		X	X			
Distress, anxiety, stress, depressive symptoms, resilience, sleep, eating, mindfulness, emotion regulation, interoception, decentering, self-esteem, personality	X		X			
Satisfaction			X			
Meditation practice		X	X	X	X	X

Figure 2. Overview of Mindfulness Trial using the SPIRIT template of recommended content for the schedule of enrolment, interventions, and assessments (Aw et al., 2013)

^a n = 52, Wave 1 only

Figure 3. Best Practices in Generating Synthesis-Ready Research applied to Mindfulness Trial

Both the full raw dataset and the finalized analytical dataset used in this analysis are available from Zenodo (DOI: 10.5281/zenodo.4011716), along with comprehensive data dictionaries and crosswalks.

Figure 4. Data availability statement for Mindfulness Trial

<p>Study description</p> <p>Taken from the <code>study_protocol.docx</code> document, which describes the study approach in detail:</p> <p>"Young adults in college experience high levels of stress, anxiety, and depression, which can lead to maladaptive behaviors and chronic health issues including inflammation and HPA-axis dysregulation. University mental health centers are seeking effective programs that teach coping skills to self-manage stress, with low stigma, that are easy to implement in large scale. The aim of this protocol is to describe the design of a study aiming to evaluate the effectiveness of a one-month self-guided meditation program for university students comparing various tools to improve mental health, physical health and health behaviors, and explore moderators. Secondary aims include reaching a diverse audience and documenting adverse experiences."</p> <p>(a)</p>	<p>PICOTS</p> <p>Population - 140 university undergraduate or postgraduate students studying at an American university.</p> <p>Intervention - 10 minutes of self-guided meditation daily for four weeks, facilitated by the 10% Happier App, in combination with neurofeedback from the Muse Neurofeedback Tool.</p> <p>Comparison - 10 minutes of self-guided meditation daily for four weeks, facilitated by the 10% Happier App.</p> <p>Outcomes - Outcome measures included those related to Personality, Stress, Distress, Resilience (coping), Mindfulness, Emotion regulation, Sleep, Self-Regulation of Eating, Motivation Survey, and Student Adherence (for more details, see Section 2.4 of the <code>study_protocol.docx</code> document and the <code>Instrument_List.xlsx</code> document).</p> <p>Time - 4 week intervention followed by post-intervention surveys (1-, 6- and 12-months). See <code>Study Timeline.xlsx</code> for more details on the tasks performed and the data collected at each timepoint.</p> <p>Study Design - randomized controlled trial with two intervention groups</p> <p>(b)</p>
<p>Data source files</p> <p>All data files are available as Excel spreadsheets in the <code>data/</code> subdirectory. The relationships between each data file, and between data files and other information contained in this repository, are described below:</p> <ul style="list-style-type: none"> • <code>RECAP_data.xlsx</code> (Data dictionary: <code>Data Dictionary for REDCAP Data.pdf</code>) contains the raw survey data exported from the REDCAP software. • <code>External_data.xlsx</code> (Data dictionary: <code>Data Dictionary for External Data.xlsx</code>) contains additional variables on each participant which were not captured by the REDCAP survey. Note some variables, such as C-Reactive protein or cortisol levels, are only available for a subset of participants, based on the availability of saliva samples for that participant. See Section 2.2.1 in <code>study_protocol.docx</code> for more details. • <code>Combined_data.xlsx</code> was created by merging the <code>RECAP_data.xlsx</code> and <code>External_data.xlsx</code>, and is used as the complete dataset from which composite variables are created using the <code>create_composite_variables.do</code> STATA do file. The crosswalk between the individual measures and the composite variables are described in more detail in <code>Stata Variable Crosswalk.xlsx</code> • <code>Debriefing Interview - Wave 1.xlsx</code> : contains qualitative responses from "Wave 1" participants to the debriefing interview questions. <i>Note: the interview was only done for Wave 1 participants.</i> <p>(c)</p>	<p>Permanent contact about this data</p> <p>Rebecca L. Acobonuk, University of Connecticut, Institute for Collaboration on Health, Intervention, & Policy, Department of Psychological Sciences, United States. ORCID: 0000-0001-8254-2396</p> <p>Licence</p> <p>The materials in this repository are licensed under the Creative Commons Attribution 4.0 (CC-BY-4.0) International. The full license file can be found here.</p> <p>(d)</p>

Figure 5. Mindfulness trial metadata included in the README file. Panels (a) and (b) provide the study description according to the PICOTS framework; (c) provides data source files, locations, and relationships between the files; (d) provides permanent author information and licensing information.

Table 1. Demonstration of use of `litsearchr` to produce key terms

Database	Search Strategy	Top 50 Keywords, ranked from greatest to least important		
PubMed (373 results)	(((university student[Title/Abstract]) OR (college student[Title/Abstract])) AND (mindfulness[Title/Abstract]) OR (meditation[Title/Abstract]) AND (apps[Title/Abstract]) OR (phone application[Title/Abstract]))	phone application mobile phone mobile phone application controlled trial mobile app trial registration randomized control randomized controlled randomized controlled trial control group trial background mobile application smartphone app smart phone quality of life controlled trial background smart phone application mental health	primary outcome pilot study intervention group mobile health secondary outcome health intervention phone applications secondary outcomes study protocol health care clinical trial randomized controlled trial background randomised controlled trial randomised controlled health service physical activity data collection	mobile phones study background smartphone application mobile phone applications health problem study aimed participants completed based intervention health outcomes focus group outcome measure health application outcome measures public health outcomes include
PubMed (1589 results)	(((((((university[Title/Abstract]) OR (college[Title/Abstract])) AND (mindfulness[Title/Abstract]) OR (meditation[Title/Abstract]) AND (treatment[Title/Abstract]) OR (intervention[Title/Abstract]) OR (program[Title/Abstract]) AND (apps[Title/Abstract]) OR (phone application[Title/Abstract]))	controlled trial randomized control mobile app randomized controlled randomized controlled trial mobile phone trial registration smartphone app phone application mobile health health app mobile phone app physical activity mobile apps primary outcome trial background control group health intervention	clinical trial health care systematic review controlled trial background based intervention controlled trials health apps intervention group study background secondary outcome mental health randomized controlled trial background smartphone apps health interventions clinical trials quality of life randomised control	mobile phone application randomised controlled outcome measure randomised controlled trial mobile application study aimed behavior change secondary outcomes data collection smartphone application review background mhealth app health outcome phone applications health outcomes
PubMed (4664 results)	(((eeg[Title/Abstract]) OR (neurofeedback[Title/Abstract]) AND (RCT[Title/Abstract])) OR (randomized controlled trial[Title/Abstract]) AND (mental health[Title/Abstract]) AND (mindfulness[Title/Abstract]) OR (meditation[Title/Abstract]))	controlled trial randomized control mindfulness meditation randomized controlled control group randomized controlled trial quality of life stress reduction mental health meditation practice based intervention outcome measure based stress based stress reduction	mindfulness-based stress reduction pilot study systematic review significant improvement randomly assigned perceived stress based interventions significant difference mindfulness training mindfulness-based intervention meditation training trial registration	secondary outcome month follow depressive symptom results suggest heart rate trial background active control depressive symptoms mindfulness-based interventions transcendental meditation intervention group mindfulness practice

	ct])	controlled trials primary outcome outcome measures clinical trial	statistically significant present study blood pressure randomized controlled trials	findings suggest showed significant significant reduction significant differences
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Note. For the full instructions, including R syntax and our citation files, see https://github.com/mcguinlu/prevsci-data-sharing-exemplar/tree/master/keyword_generation

Table 2. Comparison of the options for sharing data

Location	Examples	Advantages	Disadvantages	Examples
Non-affiliated repositories	Zenodo; Dryad; Figshare; Open Science Framework	Free (except Dryad). Self-archiving. DOI assigned. Long-term storage. Can blind repositories for double-blind peer-review (Anonymous Github; OSF “Anonymous” Links)	Some have a Data Publishing Charge (e.g., Dryad charges \$120). No review of files uploaded.	Repository for Abbott et al., 2019, contains raw dataset, analysis dataset, cleaning code, analysis code. Available from 10.5281/zenodo.3529382
Institutional repositories	data.bris; Harvard Dataverse	Supported by institution. DOI assigned. Often can get help from staff when uploading data.	Not as well known as other repositories - limits Findability.	Pescosolido et al., 2020, contains scripts and data to replicate all figures/analyses found in the original manuscript.
Supplemental files	Any file (.txt, .xlsx, .doc, .pdf) with data and attached to the online version of the published article	Likely relatively less work to prepare compared to the other options	No DOI (for data). Can be closed-access. Potential for data to be lost. Least findable of the other options.	Slep et al., 2020, contains mPLUS code and data Tomczyk et al., 2020, open access, includes data in manuscript and supplemental files



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Supplementary Material

SPIRIT-CONSORTSPI_ES-map_15sep2020.docx

