Assessing markers of reproducibility and transparency in smoking cessation behaviour change intervention evaluations (2018-2019)

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Abstract

Introduction: Activities promoting research reproducibility and transparency are crucial. Evaluation of smoking cessation interventions is one area where vested interests may motivate reduced reproducibility and transparency.

Aims: Assess markers of transparency and reproducibility in smoking cessation behaviour change intervention evaluation reports.

Methods: One hundred evaluation reports of smoking cessation behaviour change intervention randomised controlled trials published in 2018-2019 were identified. Reproducibility markers of pre-registration, protocol sharing, data-, materials- and analysis script-sharing, replication of a previous study and open access publication were coded in identified reports. Transparency markers of funding source and conflict of interest declarations were also coded. Coding was performed by two independent researchers, with inter-rater reliability calculated using Krippendorff’s alpha.

Results: Seventy-one percent of reports were open access and 73% pre-registered. However, only 13% provided accessible materials, 7% accessible data and 1% accessible analysis scripts. No reports
REPRODUCIBILITY & TRANSPARENCY OF SMOKING CESSATION INTERVENTIONS

were described as replication studies. Ninety-four percent of reports provided a funding source statement and eighty-eight percent of reports provided a conflict of interest statement.

**Conclusions:** Open data, materials, analysis and replications are rare in smoking behaviour change interventions, whereas funding source and conflict of interest declarations are common. Future smoking cessation research must be more reproducible to facilitate knowledge building.
Introduction

Researchers are becoming increasingly aware of the importance of reproducibility and transparency in scientific research and reporting (Munafò et al., 2017; Nosek et al., 2015). A well-documented ‘replication crisis’ in psychology and other disciplines has shown that engrained academic incentives encouraging novel research has led to biased and irreproducible findings (Ioannidis, 2005; John, Loewenstein, & Prelec, 2012; Nosek et al., 2012; Open Science Collaboration, 2015). Researchers, journals and funders across psychology and health sciences are now reforming scientific practice to improve the credibility and accessibility of research (Munafò et al., 2017; Norris & O’Connor, 2019).

‘Open Science’, where some or all parts of the research process are made publicly and freely available, is essential for increasing research transparency, credibility, reproducibility and accessibility (Kathawalla, Silverstein & Syed, 2020). Reproducibility-facilitating research behaviours are varied and occur throughout the research life-cycle. During study design; pre-registration and protocols specify the hypotheses, methods and analysis plan to be used in proposed subsequent research in repositories such as the Open Science Framework and AsPredicted. During data analysis, analysis scripts can be made more reproducible by marking their code with step-by-step comments to improve clarity and replication (van Vliet, 2020). During dissemination, the materials (such as intervention materials, questionnaires used), data and analysis scripts can be made available by uploading to repositories such as Open Science Framework or GitHub (Klein et al., 2018), facilitating the replication of effective research and interventions (Heirene, 2020). Allowing data and trial reports to be made available regardless of their findings enables a more accurate picture of the full state of research, minimising the ‘file drawer’ problem by which positive findings are more likely to be published than negative findings (Rotton, Foos, Van Meek & Levitt, 1995). Transparency-facilitating research behaviours include reporting sources of research funding and conflicts of interest (Fontanarosa, Flanagin, & DeAngelis, 2005; Smith, 1998). These are important in that they
help readers to make an informed judgement about potential risks of bias (Cristea & Ioannidis, 2018).

Markers of reproducibility and transparency have been assessed in domains of psychology and life sciences. A recent study exploring 250 psychology studies published between 2014 and 2017 found transparency and reproducibility behaviours to be infrequent (Hardwicke et al., 2020). Although public availability of studies via open access was common (65%), sharing of research resources was low for materials (14%), raw data (2%) and analysis scripts (1%). Pre-registration (3%) and study protocols (0%) were also infrequent (Hardwicke et al., 2020). Transparency reporting was also inconsistent for funding statements (62%) and conflict of interest disclosure statements (39%) (Hardwicke et al., 2020). Meta-science studies have assessed reproducibility and transparency across other disciplines, such as social sciences (Hardwicke et al., 2019), biomedicine (Wallach et al., 2018) and biostatistics (Rowhani-Farid & Barnett, 2018). Other research has focused on the prevalence of specific reproducibility behaviours, such as the prevalence of open access publications being around 45% across scientific discipline assessed in 2015 (Piwowar et al., 2018).

However, the extent of reproducibility and transparency behaviours in public health research, including smoking cessation, is currently unclear. A recent investigation of randomised controlled trials addressing addiction found data sharing to be non-existent, with 0/394 trials making their data publicly available (Vassar, Jellison, Wendelbo, & Wayant, 2020). Markers of wider reproducibility behaviours are yet to be assessed. Transparent reporting in terms of funding and conflicts of interest is especially crucial for smoking cessation, where tobacco and pharmaceutical companies fund some research directly or indirectly (Garne, Watson, Chapman, & Byrne, 2005). Such vested interests may distort the reporting and interpreting of results and this may especially be the case in areas of controversy such as e-cigarette research (Heirene, 2020; Munafò & West, 2020; Smith, 1998; West,
The aim of the current study is to assess markers of i) reproducibility, and ii) transparency within smoking cessation intervention evaluation reports.

Methods

Study design

This was a retrospective observational study with a cross-sectional design. Sampling units were individual behaviour change intervention reports. This study applied a methodology used to assess reproducibility and transparency in the wider psychological sciences (Hardwicke et al., 2020) and social sciences (Harwicke et al., 2019). This study was pre-registered: https://osf.io/yqi5p.

Sample of reports

The Cochrane Tobacco Group Specialised Register of controlled trials was searched in November 2019, identifying 1630 reports from 2018 & 2019. Inclusion criteria were randomised controlled trials published in 2018 and 2019, included in the Human Behaviour-Change Project (Michie et al., 2017; https://osf.io/efp4x/). Exclusion criteria were trial protocols, abstract-only entries and economic or process evaluations. Of the 157 reports remaining after applying these criteria, 100 reports were selected using a random number generator and PDFs obtained from journal websites.

Measures

Article characteristics recorded were: i) 2018 journal impact factor for each report using the Thomson Reuters Journal Citation Reports facility, and ii) country of the corresponding author (Table 1).

Markers of research reproducibility were assessed by recording presence of the following in included reports: i) Pre-registration: whether pre-registration was reported as carried out, where the pre-
registration was hosted (e.g Open Science Framework, AsPredicted), whether it could be accessed and what aspects of the study were pre-registered; ii) Protocol sharing: whether a protocol was reported as carried out and what aspects of the study were included in the protocol; iii) Data sharing: whether data was available, where it was available (e.g online repository such as Open Science Framework, upon request from authors, as a journal supplementary file), whether the data was downloadable and accessible, whether data files were clearly documented and whether data files were sufficient to allow replication of reported findings; iv) Materials sharing: whether study materials were available, where they were available (e.g online repository such as Open Science Framework, upon request from authors, as a journal supplementary file) and whether the materials were downloadable and accessible; v) Analysis script-sharing: whether analysis scripts were available, where they were available (e.g online repository such as Open Science Framework, upon request from authors, as a journal supplementary file) and whether the analysis scripts were downloadable and accessible; vi) Replication of a previous study: whether the study claimed to be a replication attempt of a previous study; and vii) Open access publication: whether the study was published as open access.

Markers of research transparency was assessed by recording presence of the following in included reports: i) Funding sources: whether funding sources were declared and if research was funded by public organisations (such as research councils or charities), pharmaceutical, tobacco or other companies; ii) Conflicts of interest: whether conflicts of interest were declared and whether conflicts were with public organisations (such as research councils or charities), pharmaceutical, tobacco or other companies. All measured variables are shown in Table 1.

Procedure

Data collection took place between February and March 2020. Data for all measures were extracted onto a Google Form (https://osf.io/xvwjz/). All reports were independently coded by two
researchers (YH & RL). Any discrepancies were resolved through discussion, with input from a third researcher if required (EN).

Analysis

Research reproducibility was assessed using the markers of pre-registration, sharing of protocols, data, materials and analysis scripts, replication and open-access publishing (Table 1). Research transparency was assessed using the markers of funding source and conflicts of interest declarations. Inter-rater reliability of the independent coding of the two researchers was calculated using Krippendorff’s alpha (Hayes & Krippendorff, 2007) using Python 3.6 (https://github.com/HumanBehaviourChangeProject/Automation-InterRater-Reliability).

Results

Inter-rater reliability was assessed as excellent across all coding, $\alpha=0.87$. Full data provided on OSF: https://osf.io/sw63b/.

Sample characteristics

Seventy-one out of 100 smoking cessation behaviour change intervention reports were published in 2018 and 29 published in 2019. Out of the 100 reports, four had no 2018 journal impact factor, with the remaining 96 reports having impact factors ranging from 0.888 to 70.67 (Mean = 4.95). Fifty-four out of 100 reports took place in the United States of America (https://osf.io/j2zp3/).
Markers of reproducibility in smoking cessation behaviour change intervention evaluation reports

Final reconciled coding of reproducibility and transparency for all smoking cessation behaviour change intervention reports can be found at: https://osf.io/jcgx6/.

Article availability (open access)

Seventy-one out of 100 smoking cessation behaviour change intervention reports were available via open access, with 29 were only accessible through a paywall (Figure 1A).

Pre-registration

Seventy-three out of 100 smoking cessation behaviour change intervention reports stated that they were pre-registered, with 72 of these being accessible. Fifty-five studies were pre-registered at ClinicalTrials.gov, eight at the International Standard Randomized Clinical Trial Number registry (ISRCTN), the Australian and New Zealand Clinical Trials Registry (ANZCTR), Chinese Clinical Trial Registry (ChCTR), Netherlands Trial Register (NTR), Iranian Clinical Trials Registry (IRCT), Clinical Research Information Service in Korea (CRIS) or the UMIN Clinical Trials Registry in Japan (UMIN-CTR).

All of the 72 accessible pre-registrations reported methods, with 2 also reporting hypothesis. Only two accessible pre-registrations included hypothesis, methods and analysis plans. Twenty-six of the 100 reports did not include any statement of pre-registration. One report stated the study was not pre-registered (Figure 1B).

Protocol availability

Seventy-one out of 100 smoking cessation behaviour change intervention reports did not include a statement about protocol availability. For the 29 reports that included accessible protocols, 23 had a protocol that included hypothesis, methods and analysis plans. Three reports only had methods in
their protocol, whereas two of them included both hypothesis and methods, and one of them included methods and analysis plans (Figure 1C).

**Material availability**

Twenty-two out of 100 reports included a statement saying the intervention materials used were available. Sixteen of these reports provided materials via journal supplementary files and six reports stated that their materials were only available upon request from the authors (Figure 1D).

**Data availability**

Sixteen out of 100 reports included a data availability statement. Nine reports stated data was available upon request from the authors and one stated the data was not available. The remaining six articles included their data in the supplementary files hosted by the journals, but one article’s data file could not be opened. Four of the remaining articles had clearly documented data files, but only two of them contained all necessary raw data. As such in total, only seven reports provided links to data that was actually accessible (Figure 1E).

**Analysis script availability**

Three out of 100 reports included an analysis script availability statement. However only one provided accessible script as a supplementary file, with the remaining two stating analysis script was available upon request from authors (Figure 1F).

**Replication study**

None of the 100 smoking cessation behaviour change intervention reports were described as replication studies (Figure 1G).
Markers of transparency in smoking cessation behaviour change intervention evaluation reports

Final reconciled coding of reproducibility and transparency markers for all smoking cessation behaviour change intervention reports can be found at: https://osf.io/jcgx6/.

Funding

Ninety-four of the 100 smoking cessation behaviour change intervention reports included a statement about funding sources. Most of the reports disclosed public funding only such as via government-funded research grants, charities or universities (n=80). Eight reports disclosed both public funding and funding from private companies. Five reports disclosed funding from private companies only, including pharmaceutical (n=3), tobacco companies (n=1) and other companies (n=1). One report reported receiving no funding (Figure 1H).

Conflicts of interest

Eighty-eight of the 100 articles provided a conflict of interest statement. Most of these reports reported that there were no conflicts of interests (n=51). Thirty-seven reports reported that there was at least one conflict of interest, including from a pharmaceutical company (n=27), private company (n=17), public organization (n=13) and tobacco company (n=3) (Figure 1I).

Discussion

This assessment of 100 smoking cessation behaviour change intervention evaluation reports identified varying levels of research reproducibility markers. Most reports were open access and pre-registered; however, research materials, data and analysis scripts were not frequently provided and
no replication studies were identified. Markers of transparency assessed here by funding source and conflicts of interest declarations were common.

**Assessment of reproducibility markers in smoking cessation behaviour change intervention evaluation reports**

Pre-registration, as a marker of research reproducibility, was found to be higher for smoking cessation interventions (73%) than in wider psychological research (3%) (Hardwicke et al., 2020). Open access reports were at similarly moderate levels (71%) to psychology (65%) (Hardwicke et al., 2020), but greater than the 45% observed in the social sciences (Hardwicke et al., 2019), 25% in biomedicine (Wallach et al., 2018) and 45% across scientific literature published in 2015 (Piwowar et al., 2018). This high rate of open access publishing in smoking cessation interventions may reflect increasing requirements by health funding bodies for funded researchers to publish in open access outlets (Severin, Egger, Eve, & Hürlimann, 2020; Tennant et al., 2016) and increasing usage of pre-print publication outlets such as PsyArXiv for the psychological sciences and MedRxiv for medical sciences.

The rate of open materials was lower than in biomedicine (13% vs 33%) (Wallach et al., 2018) but similar to the social sciences rate of 11% (Hardwicke et al., 2019). Open analysis scripts were found to be as infrequently provided in smoking cessation interventions as in wider psychological research (both 1%) (Hardwicke et al., 2020), social sciences (Hardwicke et al., 2019) and biostatistics (Rowhani-Farid & Barnett, 2018).

Open data of smoking cessation interventions was found to be very low (7%), but greater than the 0% estimate in a larger sample of 394 smoking trials (Vassar et al., 2020) and to the 2% of wider psychological research (Hardwicke et al., 2020). Raw data are essential for meta-analyses to make sense of the diverse smoking cessation evidence. Common barriers for including studies in meta-
analyses include a lack of available data, often after requests from authors (Greco, Zangrillo, Biondi-Zoccai, & Landoni, 2013; Ioannidis, Patsopoulos, & Rothstein, 2008). Provision of raw data as supplementary files to published intervention reports or via trusted third-party repositories such as the Open Science Framework (Klein et al., 2018) is important to facilitate evidence synthesis, especially in a field as important for global health as smoking cessation.

No replication attempts were identified in this sample of smoking cessation intervention reports, compared to 5% in wider psychology studies (Hardwicke et al., 2020) and 1% in the social sciences (Hardwicke et al., 2019). This lack of replication may be due to a lack of available resources of smoking interventions to facilitate replication, as identified in this study, or may reflect a lack of research prioritisation and funding for replication, with novel rather than confirmatory research prioritised at global, institutional levels (Munafò et al., 2017; Open Science Collaboration, 2015).

Assessment of transparency markers in smoking cessation behaviour change intervention evaluation reports

Declaration of funding sources and conflicts of interest, as markers of research transparency, were found here to be commonly provided in smoking cessation intervention evaluation reports. Funding sources were declared in more smoking cessation reports (95%) than wider psychology (62%) (Hardwicke et al., 2020), social sciences (31%) (Hardwicke et al., 2019) and biomedical science reports (69%) (Wallach et al., 2018). Similarly, a statement on conflicts of interest was provided more commonly in smoking cessation (88%) than wider psychology (39%) (Hardwicke et al., 2020), social sciences (39%) (Hardwicke et al., 2019) and biomedical sciences reports (65%) (Wallach et al., 2018). 17% of studies reported conflicts from private companies and 3% from tobacco companies. The comparatively high level of transparency markers observed here in smoking cessation interventions compared to other fields is likely to reflect improved reporting following previous
controversies in the field (Bero, 2005; Garne et al., 2005; Malone & Bero, 2003). Funding and disclosure statements are now commonly mandated by journals related to smoking cessation (Cristea & Ioannidis, 2018; Munafò & West, 2020; Nutu, Gentili, Naudet, & Cristea, 2019).

**Strengths and limitations**

A strength of this study is its use of double-coding by two independent researchers of all reproducibility and transparency markers, enabling inter-rater reliability assessment. A limitation is that this study is based on a random sample of 100 evaluation reports of smoking cessation behaviour change interventions, whereby assessments of reproducibility and transparency may not be generalizable to broader smoking cessation interventions. Secondly, markers of reproducibility and transparency were dependent on what was described within evaluation reports. Direct requests to authors or additional wider searching of third-party registries such as Open Science Framework may have identified additional information indicating reproducibility.

**Future steps to increase reproducibility and transparency of smoking cessation interventions**

Urgent initiatives are needed to address the low levels of reproducibility markers observed here in smoking cessation research, especially in the areas of open materials, data, analysis scripts and replication attempts. As with any complex behaviour change, this transformation requires systems change across bodies involved in smoking cessation research: researchers, research institutions, funders, journals and beyond (Munafò et al., 2017; Norris & O’Connor, 2019). Interventions are needed to increase the capability, opportunity and motivation of these bodies to facilitate behaviour change towards reproducible research in smoking cessation (Michie, van Stralen, & West, 2011). For example, capability can be addressed by providing researcher training, equipping them with the skills needed to make their research open and reproducible, such as how to use the Open Science Framework, pre-print servers and how to make their analysis reproducible. Opportunity to engage in reproducible research in smoking cessation interventions can be facilitated within institutions,
facilitating discussions around Open and reproducible working (Orben, 2019) and developing a culture around valuing progressive and open research behaviours (Norris & O’Connor, 2019).

Motivation to research reproducibly can be addressed by providing researcher incentives (Norris & O’Connor, 2019). Open Science badges recognising open data, materials and pre-registration have been adopted by journals as a simple, low-cost scheme to increase researcher motivation to engage in these reproducibility behaviours (Kidwell et al., 2016). Open Science badges have been identified as the only evidence-based incentive program associated with increased data sharing (Rowhani-Farid, Allen, & Barnett, 2017). However, although adoption of Open Science badges in smoking cessation journals is currently low, indicating this as one important initiative currently missing for journals in smoking cessation. Future research could compare this study’s baseline assessment of reproducibility and transparency markers in smoking cessation intervention evaluation reports to assess changes in reporting and researcher behaviour.

**Conclusions**

Reproducibility markers of smoking cessation behaviour change intervention evaluation reports were varied. Pre-registration of research plans and open access publication were common, whereas the provision of open data, materials and analysis was rare and replication attempts were non-existent. Transparency markers were common, with funding sources and conflicts of interest usually declared. Urgent initiatives are needed to improve reproducibility in open materials, data, analysis scripts and replication attempts. Future research can compare this baseline assessment of reproducibility and transparency in the field of smoking cessation to assess changes.

**Acknowledgements.** Thanks to Ailbhe N. Finnerty for calculating inter-rater reliability.
Pre-registration: This study was pre-registered at: https://osf.io/yqj5p.

Data availability statement. All data are provided on OSF: https://osf.io/5rwsq/.

Financial support. Emma Norris was employed during this study on The Human Behaviour-Change Project, funded by a Wellcome Trust collaborative award (grant number 201,524/Z/16/Z).

Conflict of Interest. RW has undertaken research and consultancy for companies that develop and manufacture smoking cessation medications (Pfizer, J&J and GSK). He is an unpaid advisor to The UK’s National Centre for Smoking Cessation and Training and a Director of the not-for-profit Community Interest Company, Unlocking Behaviour Change Ltd. No other competing interests to disclose.

References


Table 1. Measured variables and operationalization.

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**Coder instructions**: Check the article for a data availability statement/link. They are often located in the “supplementary material”, “acknowledgements”, “author notes”, “methods”, or “results” sections. Search the article for the text “data availab” (to cover “data availability” and “data available”).

### Data availability statement
Does the article state whether or not data are available?
- Yes - the statement says that the data (or some of the data) are available
- Yes - the statement says that the data are NOT available
- No - there is no data availability statement
- Other*

### Data sharing method
How does the statement indicate the data are available?
- Upon request from the authors
- Personal or institution website
- An online, third-party repository (e.g., OSF, FigShare etc.)
- supplementary materials hosted by the journal
- Other*

### Data accessibility
Can you access, download, and open the data files?
- Yes / No / Other*

### Data documentation
Are the data files clearly documented?
- Yes / No / Other*

### Data content
Do the data files appear to contain all of the raw data necessary to reproduce the reported findings?
- Yes / No / Unclear / Other*

### Materials sharing
**Definitions**: “materials” refers to any study items that would be needed to repeat the study, such as stimuli, survey instruments, and computer code/software used for data collection, presentation stimuli or running experiments.

#### Materials availability statement
Does the article state whether or not materials are available?
- Yes - the statement says that the materials (or some of the materials) are available
- Yes - the statement says that the materials are NOT available
- No - there is no materials availability statement
- Other*

#### Materials sharing method
According to the statement, how are the materials accessible?
- Upon request from the authors
- Personal or institution website
- An online, third-party repository (e.g., OSF, FigShare etc.)
- supplementary materials hosted by the journal
- Other*
## Materials accessibility

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## Analysis script sharing

**Definition:** "Analysis scripts" refers to specification of data preparation and analysis steps in the form of highly detailed step-by-step instructions for using point-and-click software, analysis code (e.g., R), or syntax (e.g., from SPSS).

**Coder instructions:** Check the article for an analysis script availability statement/link. They are often located in the "supplementary material", "acknowledgements", "author notes", "methods", or "results" sections. Search for the text "analysis script" and "analysis code".

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## Replication

**Definitions:** “replication” refers to repetition of a previous study’s methods in order to ascertain whether similar findings can be obtained.

**Coder instructions:** Search the abstract and introduction for the phrase “replicat” (to cover ‘replication’, ‘replicates’ etc). Confirm the authors are using the phrase with the definition provided above.

### Replication statement

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## Open access

**Coder instructions:** To establish the open access status of the article: Go to [https://openaccessbutton.org/](https://openaccessbutton.org/) and enter the article’s doi (e.g., “10.1371/journal.pcbi.1004574”) if available (if not, enter the article title). If a link is provided, check that you can access the article at the link. If the article is accessible answer “Yes”. If the article is not accessible at the provided link, or no link is provided, answer “No”.

### Open access status

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*If a response marked with an asterisk is selected, the coder is asked to provide more detail in a free-text response box.

**Note:** Identified measured variables have been adapted from a previous study assessing the transparency and reproducibility in psychological sciences (Hardwicke et al. 2020).
Figure 1. Overview of reproducibility and transparency markers in smoking cessation interventions.