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Testing a novel implementation imagery e-health intervention to change driver behaviour during floods: A randomised controlled trial protocol

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Testing a novel implementation imagery e-health intervention to change driver behaviour

during floods: A randomised controlled trial protocol

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Abstract

Introduction: Drowning due to driving into floodwater accounts for a significant proportion of all deaths by drowning. Despite awareness campaigns such as 'If it's flooded, forget it', people continue to drive into floodwater. This causes loss of life, risk to rescuers, and damage to vehicles. The aim of this study was to develop and evaluate an online e-health intervention to promote safe driving behaviour during flood events.

Methods and analysis: The study is conducted in two phases. Phase I involves the development and optimisation of the intervention content through expert review and pilot testing. Phase II is a 2x3 randomised controlled trial in which participants are randomised into one of two conditions: (1) education about the risks of driving into floodwater; or, (2) education about the risks of driving into floodwater plus a theory-based behaviour change intervention using planning and imagery exercises.

Ethics and dissemination: The study has been approved by the Griffith University Human Research Ethics Committee. Participants will review a study information sheet and provide informed consent prior to commencing participation. Results will be disseminated through peer-reviewed publications, industry reports, media releases, and at academic conferences. Deidentified data will be made publicly available following publication of the results.

Trial Registration: ACTRN12618001212246
Available at: http://www.ANZCTR.org.au/ACTRN12618001212246.aspx

Keywords: Flooded waterways; social cognitive theories; driving; drowning, water safety; mental imagery

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Article Summary
- The study intervention is theory-based, consisting of a novel integration of effective behaviour change strategies.
- The study will use a sample with key demographic characteristics proportional to the Australian population, ensuring that the results are generalisable.
- While the outcomes are an extensive range of psychological variables established to predict driving into floodwater, the unpredictable occurrence of flood events means that examining the effect of our intervention on actual behaviour is not feasible within the timeframe of the study.

Introduction

Drowning is the third leading cause of injury-related deaths worldwide [1] and the leading cause of death during times of flood [2][3]. Activities such as driving into, walking near, or engaging in recreational activities near or in floodwater are commonly reported as preceding drowning [1]. Reports have shown that, in Australia, around 53% of flood-related deaths and 55% of all river flood-related unintentional fatal deaths [4] were the result of driving into floodwaters. Another recent study surveyed a more than 600 Australian river users and found 35.7% of participants reported having driven into floodwater, with males (43.9%) significantly more likely to have driven into floodwaters than females (27.8%) [5]. These drowning statistics also likely underestimate the true extent of the driving-related drownings due to limitations around the use of International Classification of Diseases (ICD) flood-related drowning codes [6][7].

Due to the magnitude of this issue, intentionally driving into floodwater has been the subject of mass-media drowning prevention campaigns such as 'Turn Around Don't Drown' [8] in the United States and 'If it's flooded, forget it' [9] in Australia. However, very little research to date has evaluated the effect of these campaigns on attitudes, motivation, and actual drowning rates. In fact, fatal and non-fatal drownings resulting from intentionally driving into floodwater continue to occur regularly [10-12]. For example, during a severe weather event in a 24-hour period, in March 2017, 108 floodwater rescues were conducted in Queensland, Australia by the State Emergency Service [13]. This has in resulted in a national call for research into behaviours around floodwater [12].

In response to a paucity of empirical research, we conducted a series of studies to understand the psychological processes underpinning decisions around driving into floodwater [14-16], avoiding driving into floodwater [17], and the experiences of those who rescue drivers who have driven into floodwater [18]. While it is commonly assumed that people choose to drive into floodwater due to a lack of awareness of the risks, our research identified that many of the

people who drive into floodwater are aware of the risks and have been exposed to relevant

mass-media campaigns [14].

Building on this research, we developed and evaluated a mass-media style infographic

video that included theory-based behaviour change methods to bridge the gap between

awareness and intentions to drive into floodwater [19]. While the video had an effect on attitudes,

subjective norm, perceived susceptibility, and perceived severity immediately post-

intervention, these effects were only maintained at the four-week follow up for women and not

men. Further, there was no effect of the video on intentions [19]. Therefore, continued

development and evaluation of interventions aimed at promoting safe driving behaviour during

floods is a priority. Some potential explanations for the null effect of the infographic on

intentions are that the intervention did not directly target intentions and/or did not aid in the

development of a plan that can be implemented if this particular situation arises for the person

during a flood event (i.e. faced with a flooded road whilst in their vehicle). We also suspect

that gender differences in the effects at follow-up may have been due to females self-

reinforcing the messages contained within the intervention due to a greater tendency to utilise

ruminative thinking styles [20]. This suggests that an effective intervention aimed at promoting

safe driving behaviour during floods should utilise behaviour change methods that aid in the

development of a plan and when to implement it, such as implementation intentions [21]; and,

allow sufficient internalisation of the intervention content through strategies such as mental

imagery [22].

Implementation intentions are concrete plans about when, where, and how to enact a

behaviour to achieve a specific goal which contrasts from simply intending to achieve a goal–

otherwise known as goal intentions [23]. Implementation intentions have been found to be

superior to goal intentions in achieving goals, with a meta-analysis finding medium to large

effects of implementation intentions on goal achievement [24]. Conroy and Hagger [22] describe

mental imagery interventions as involving "self-directed imagining or visualizing specific

events, actions, or outcomes, including concomitant feelings and responses, with the express

purpose of increasing motivation toward a target action or task" (p. 669). Conroy and Hagger's

(2018) meta-analysis of imagery interventions in health behaviour found nontrivial small

averaged corrected effects of these interventions on post-intervention behaviours, intentions,

perceived control, and attitudes; and, identified characteristics of interventions that moderate

the effect size. A small number of studies have combined implementation intentions and

mental imagery to change health behaviours such as fruit and vegetable consumption [25] and

alcohol intake [26] yielding small to medium effect sizes. In building upon our prior work [19], we

therefore seek to combine two behaviour change strategies–mental imagery and

implementation intentions–to develop an *implementation imagery* intervention to promote less

favourable intentions to drive into floodwater.

Objectives

Drawing on our previous research [14-19] we aim to develop a theory-based behavioural

intervention to promote less favourable intentions of drivers to drive into floodwaters. The

research will be conducted in two phases, a development phase in which the theory-based

content of the implementation imagery intervention embedded in a survey will be developed

and piloted, and an implementation and evaluation phase in which the effect of the intervention

in changing intentions and beliefs with respect to driving into floodwaters, will be tested in a

population of drivers using a randomised controlled design. Drivers recruited to the trial are

randomly assigned to intervention or control conditions. Participants assigned to the

implementation imagery condition receive a set of education-based messages that focus on

changing attitudes and intentions with respect to driving into floodwaters, and the theory-based

implementation imagery exercises. The control condition comprises the education-based

messages alone. Specifically, the objectives of the current study are to: (a) test the effectiveness

of the intervention administered after baseline measures of study constructs at Time 1 (T1) in

changing drivers' intentions and beliefs immediately post-intervention at Time 2 (T2); (b)

determine whether the effects of the intervention are maintained four weeks later at Time 3

(T3); compare the effects of the intervention to effects of a comparison condition comprising

publicly available education on driving into floodwater; and, (d) examine gender differences in

intervention effects at T2 and T3.

We hypothesise that drivers assigned to the intervention condition will report

significantly lower intentions to drive through floodwater, relative to the control condition

immediately post-intervention at T2 (primary outcome; Hypothesis 1). With regard to the

secondary outcomes, we hypothesise that drivers assigned to the intervention condition will

report significantly less favourable attitudes and reduced perceived social pressure to drive

through floodwater, as well as greater perceptions of behavioural control, risk perception,

perceived susceptibility, perceived severity, and anticipated regret toward driving through

floodwater, relative to the control condition immediately post-intervention at T2 (Hypothesis

2). We further hypothesise that that drivers assigned to the intervention condition will report

significantly greater barrier self-efficacy and action planning regarding avoiding driving

through floodwater, relative to the control condition immediately post-intervention at T2

(Hypothesis 3). We also expect that the effects of the intervention will be maintained four-

weeks later at T3 (Hypothesis 4). Given our previous research has identified gender differences

in changing beliefs [19], we will also test for sex differences in the effects of the intervention on

study outcomes.

Methods and Analysis

The study protocol is reported in accordance with SPIRIT Statement standard protocol

items for clinical trials [27 28].

Intervention Development and Optimisation

The intervention content was developed based on existing safety messages [9], our prior

research [14 17], behaviour change methods [29], and best-practice techniques for implementation

intentions and mental imagery [22]. Prior to recording, the scripts were reviewed by a panel of

experts in drowning prevention, behaviour change, and media and communication. The scripts

were also piloted with two Australian drivers and feedback was invited. Based on initial expert

and driver feedback, refinements to wording of the scripts were made. The scripts were then

audio-recorded using a voiceover actor and developed into videos. The videos then underwent

further expert review and piloting with eight drivers from the target population. The pilot

involved the participants completing the T1 survey, the intervention, the T2 survey, and then a

semi-structured interview where they were asked broadly about their thoughts regarding the

exercises. The participants were probed for specific information regarding clarity and timing of

the different exercises in the video if it was not already shared. The drivers were purposively

recruited to ensure a range on key demographic factors of age, sex, and education level. Based

on qualitative feedback provided by pilot participants, we made data-driven refinements to the

presentation and timing allocated to the exercises.

Patient and Public Involvement

Patient and public involvement in the development of the intervention was conducted

through our prior research which involved qualitative interviews with members of the target

population [14 17]—Australian drivers—and through piloting of the intervention materials with

Australian drivers. Specifically, drivers' descriptions of the behaviour informed the wording

of the items used in the outcome measures. Drivers' descriptions from these studies also

informed the content of the intervention. The research questions were developed around

evaluating the effect of the intervention on psychological constructs that have been found to

predict willingness to drive through floodwater in prior research [15 16]. Drivers will not be

involved in the recruitment or conduct of the study. Participants will be provided with the

contact details of the research team on the study information sheet and will be informed that

they can contact the research team if they wish to receive the results of the study. The burden

of participating will be assessed by the drivers after having read the study information and

prior to provision of informed consent.

Study Design

The intervention will be evaluated against the control condition immediately post-intervention (T2) and four-weeks later (T3). The evaluation will adopt a 2 (intervention condition: education and implementation intention imagery condition vs. education only condition) x 3 (time: T1, T2, T3) parallel group randomised controlled design. Figure 1 illustrates the design of the intervention and participant flow through the study.

INSERT FIGURE 1 ABOUT HERE

Setting and Participant Recruitment

The randomised controlled trial will be conducted using an online survey tool (Qualtrics[TM]). Participants will be eligible if they hold a valid full driver's licence and are an Australian resident. Participants will be recruited using a research panel provider and screened by the provider before entering the trial. In addition to the inclusion criteria, participants will be screened on the following demographic characteristics and quotas will be imposed to ensure that the sample comprises similar proportions of these characteristics as the general population: age, sex, geographic region (by state and metropolitan vs. rural), and household income. The study will adopt a double-blind procedure. Participants will be unaware of the condition to which they have been assigned and study purpose. Staff at the research panel company who may have direct contact with the participants will also be unaware of the conditions and purpose of the study.

Data Quality

Four questions will be embedded within the T1 survey to assess attentive responding [30] [31]. The questions instruct the choice of a particular answer so that it is not possible to answer the question incorrectly if the item is read carefully (e.g., "please choose answer Choice 2 to ensure you are paying attention"). Participants who do not answer all four of the items correctly will be excluded prior to randomisation.

Randomisation

Randomisation into one of the two groups will be conducted by the Qualtrics randomizer feature following the T1 survey. The Qualtrics randomizer operates using a Mersenne Twister pseudorandom number generator. The Mersenne Twister is the default pseudorandom number generator for a range of widely used software packages including Microsoft Excel and SPSS. By nature of this method of random assignment, the sequence cannot be determined until the participant is assigned.

Intervention Condition

Participants will be initially presented with a brief information sheet outlining study expectations and participant rights prior to completing an informed consent form. They will then watch a brief 'welcome' video to familiarise participants with the voice of the narrator, and to give participants the opportunity to enable the audio on their device prior to commencing the intervention. Next, participants will complete the T1 (pre-intervention) questionnaire, after which they will be randomised into one of two conditions (see Figure 1 for trial design). Both groups will watch the welcome video; however, the welcome video for the control group does not make reference the mental imagery activity. The intervention group will receive the following six-part procedure, while the control group will receive only Part 1. Participants are then directed to the T2 survey. See Supplementary Material A for video scripts. The intervention utilises a range of behaviour change methods [29], which have been mapped on to theoretical constructs that comprise the study outcomes (see Table 1).

Part 1: Education. The first video is designed to educate participants on the risks of driving into floodwater. It has been composed based on information that is publicly available and commonly broadcasted in Australia.

Part 2: Promoting willingness to form a goal. The second video is designed to encourage participants to form a goal to avoid driving into floodwater if they encounter it on their route. The video contains visuals of rain, floodwater, and a floodwater damaged road, and

drivers are provided with further information about why people driver into floodwater drawn

from our prior research [14 17].

Part 3: Practice imagery exercise. Prior to the process imagery exercise, participants

are provided with a practice guided imagery exercise. The purpose of the exercise is to allow

participants to familiarise them with the practice of imagery, and to get them to relax and begin

visualising vivid images. The practice guided imagery exercise prompts participants to imaging

cutting into a lemon with a knife. The exercise uses a familiar situation in order to facilitate

imagery.

Part 4: Process imagery exercise. Following the practice exercise, participants are

provided with some examples of safe options to take should they encounter floodwater on their

route. Participants are then instructed to imagine approaching floodwaters while driving their

car and selecting one of the options, and then instructed to visualise these scenes independently

for approximately two minutes. After the exercise is complete, the narrator advises the

participant that the activity is over and requests that they note down the things they imagined in

a response box alongside the video.

Part 5: Outcome imagery exercise. Participants watch a video which guides them

through an outcome imagery exercise. This involves imagining the outcomes that may occur if

they drive into floodwater, followed by a range of outcomes that would occur if they do not

drive into floodwater. After the exercise is complete, the narrator advises the participant that

the activity is over and requests that they note down the things they imagined in the space

below the video.

Part 6: Conclusion. Following the final imagery exercise, participants watch a video

thanking them for their attention and reminding them that if they are ever in the imagined

situation, to remember their goal. The purpose of this is to create a cue that may be triggered by

a situation similar to that imagined during the intervention.

Imagery Fidelity. Fidelity of the imagery intervention was assessed using four items

modified from Knäuper, et al. [25]. The items assess vividness, clarity, detail, and ease of

imagery on 7-point scales (e.g., "How CLEAR was the mental image that you had of yourself

avoiding driving through the floodwater?"). The 7-point scales vary for each item and are

described in Supplementary Material B.

Control Condition

Participants in the control group will receive the Part 1: Education video and will then

then be directed to the T2 survey. This active control condition was chosen as the comparator

to allow the effect of the imagery intervention to be examined above and beyond the effect of

simply providing information about the behaviour.

Outcomes

Psychological measures. Participants will complete measures of psychological

constructs from two social-cognitive theories: the theory of planned behaviour [32] and the health

action process approach [33]. These theories were selected because they have used to identify the

psychological determinants of a range of health and safety behaviours [34 35]. The psychological

constructs will be measured on multi-item psychometric instruments developed using

standardised guidelines (e.g., Ajzen, 2006 [36])[a]. While we discuss the behaviour in this study as

"driving into floodwater" because by nature there is no certainty around a driver making it

through, we measure the behaviour using the wording "driving through floodwater". This is

based on our prior qualitative work where participants most commonly described the behaviour

in this way [14 17]. The self-report psychological measures will be administered at T1, T2 and T3.

See Supplementary Material B for all measures used in the study.

Intention. Intention to drive through floodwater will be measured using four items

(e.g., "I intend to drive through the floodwater"). Responses are provided on 7-point scales (1 =

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[a] All scales measuring social-cognitive constructs except action planning and perceived behavioural control have been used in our previous study [19], exhibiting good internal consistency.

strongly disagree and 7 = *strongly agree*). Change in intention is the primary outcome in the

study. The following outcomes are secondary outcomes.

Attitudes. Attitudes towards driving through floodwater will be assessed using five

items preceded by the common stem: "If I were to drive through the floodwater, it would be"

Responses will be provided on semantic differential scales (e.g., 1 = *bad* and 7 = *good*).

Subjective norm. Subjective norm will be measured using five items prompting

participants to rate the extent to which important others would want them to drive through

floodwater and whether people similar to them would drive through (e.g., "Most people who

are important to me would approve of me driving through the floodwater"). Responses are

provided on 7-point scales (1 = *strongly disagree* and 7 = *strongly agree*).

Perceived behavioural control. Perceived behavioural control will be measured using

three items assessing drivers' perceptions of their ability to control the behaviour (e.g., "I have

complete control over whether I drive through the floodwater"). Responses are provided on 7-

point scales (1 = *strongly disagree* and 7 = *strongly agree*).

Risk perception. Risk perception will be measured using a two-item scale (e.g., "It

would be risky for me to drive through the floodwater". Responses are provided on 7-point

scales (1 = *strongly disagree* and 7 = *strongly agree*).

Perceived susceptibility. Perceived susceptibility will be measured using a three-item

scale (e.g., "My chances of having trouble if I drive through the floodwater are great").

Responses are provided on 7-point scales (1 = *extremely unsusceptible* and 7 = *extremely*

susceptible).

Perceived severity. Perceived severity will be measured using a two-item scale (e.g., "If

I drive through the floodwater, the consequences would be…"). Responses are provided on 7-

point scales (1 = *not at all severe* and 7 = *extremely severe*).

Anticipated regret. Anticipated regret will be measured using a three-item scale (e.g., "If I were to drive through the floodwater, I would feel regret". Responses are provided on 7-point scales (1 = *strongly disagree* and 7 = *strongly agree*).

Barrier self-efficacy. Barrier self-efficacy will be measured using nine items assessing drivers' confidence to avoid driving through floodwater (e.g., "I am confident I can avoid driving through floodwaters in the future… even when the alternative route will take more time/is inconvenient". Responses are provided on 7-point scales (1 = *strongly disagree* and 7 = *strongly agree*). The barrier self-efficacy items were developed using belief elicitation in our prior work [17] with a sample of drivers who had avoided driving into floodwater when they encountered it on their route.

Action planning. Action planning will be measured on a four-item scale (e.g., "I have made a plan regarding… How to avoid driving through floodwater"). Responses are provided on 7-point scales (1 = *not at all true* and 7 = *exactly true*).

Covariates. Consistent with the approach taken in our prior work [19], a number of demographic variables will be measured and used as covariates in the analyses. Willingness to form a goal to avoid driving through floodwater and imagery ability will also be measured and used as covariates.

Demographic and other background factors. Demographic and background details are collected at T1 including: (i) gender (0 = *male* and 1 = *female*); (ii) age (in years); (iii) relationship status (0 = *not married* and 1 = *married*); (iv) education level (0 = *non-university* and 1 = *university*); (v) number of years driving; (vi) number of children; and (vii) past frequency of driving through floodwater measured using a single item: "How often in the past 5 years have you driven through floodwater? 'Floodwater' refers to a body of water covering land that is normally dry", with responses provided on a 7-point scale (1 =*never* and 7 = *very often*).

Willingness to form a goal to avoid driving through floodwater. Following Parts 1 and

2 of the intervention (or Part 1 for the control group), participants will be asked a question to

assess their willingness to form a goal to avoid driving into floodwater, "Now that you have

heard some information about driving into floodwater, please indicate your agreement with the

following statement: I am willing to form a goal to avoid driving through floodwater",

responses provided on a 7-point scale (1 = *strongly disagree* and to 7 = *strongly agree*).

Imagery ability. Individual differences in imagery ability will be measured using a 10-

item scale drawn from the International Personality Item Pool (IPIP) [37] and designed to

measure Factor V (Intellect and Imagination) of Goldberg's Big-Five Factor Markers [38].

Responses provided on 5-point scales (1 = *very inaccurate* and 5 = *very accurate*). For

example, "Typically, I… Have a vivid imagination".

Power analysis. An *a priori* power analysis is conducted using G*Power v3.1 for an

ANCOVA model estimating fixed effects, main effects, and interactions. The effect size was

set to f = .25 (corresponding to the effect size of intention from pre- to post-intervention in

Hamilton et al., 2018 [19]) to detect a medium effect, with power set at .95 and alpha set at .01

(adjusted to protect from inflation of type I error rate due to multiple tests). Inclusion of nine

covariates was also specified. The analysis yielded a total minimum required sample size of

289. We aim to recruit 460 participants at the baseline in order to meet our target sample size

of 300 participants at the follow-up (allowing for up to 35% attrition). Recruitment of will

cease when 460 participants have participated in the baseline.

Statistical analysis. Hypotheses will be tested using a series of mixed-model

ANCOVAs. In the analyses, condition/group will be a between-participants variable; Time

(T1, T2, T3) will be a within-participants variable; and the primary outcome (intention) and

secondary outcomes (attitudes, subjective norm, perceived behavioural control, risk perception,

perceived susceptibility, perceived severity, anticipated regret, barrier self-efficacy, action

planning) will be separate dependent variables. Consistent with the approach taken in our prior

work [19], demographic variables (gender, age, relationship status, educational level, number of years driving, number of children, and past frequency of driving through floodwaters) will be included as covariates in the analyses. Mental imagery ability and willingness to form a goal to avoid driving into floodwater will also be included as covariates. Where an ANCOVA indicates that there is a significant time*group interaction for any of the outcome variables, simple effects analyses using estimated marginal means will be conducted for that outcome. Specifically, we will compare within-group differences in the outcome between time points, and between-group differences in the outcome at each time point. Alpha will be set at .01 for all analyses (adjusted to protect from inflation of type I error rate due to multiple tests). Missing data will be imputed using the Expectation-Maximisation (E-M) algorithm.

Ethics and Dissemination

Ethical approval for the study has been granted by the Griffith University Human Research Ethics Committee (GU ref no: 2017/895). We anticipate that the rigorous development and piloting process will ensure that no amendments to the protocol are required. However, if any amendments are required, they will be submitted as amendments to the Australian New Zealand Clinical Trials Registry record and reported in the final report of the study. We do not anticipate any risks greater than daily living to be involved with participation in this project, and no discomfort or adverse effects were reported by participants in the pilot study. However, participants are provided with the following information: "should you experience any discomfort due to undertaking this survey, Lifeline (13 11 14) offers a free 24-hour telephone counselling service".

Informed consent. Before being presented with the online baseline survey, participants are presented with the study information sheet. The information sheet indicates that proceeding to the next page and commencing participation will be considered consent to participate. Participants are also advised in the information sheet that they are free to cease participation at

any time without comment or penalty. See Supplementary Material C for informed consent materials.

Confidentiality. Participants will be recruited by a research panel provider and directed to an online Qualtrics survey to participate in the study. The research panel provider does not have access to participant responses, which are accessible only by members of the research team. The research team match responses using a code identifier, and the code identifier of those who complete the baseline are provided to the research panel provider to invite participants to complete the follow-up. The research team do not have access to the identities of participants.

Data deposition. Prior to publication of the results, data will be stored securely on Qualtrics and then the Griffith University Google Drive or OneDrive allocation and will be accessible only by authors K.H and J.J.K. Once data collection is complete, the data will be transferred to author M.S.H. Given the restrictions on access to the data, a data monitoring committee will not be required. Following publication, deidentified data and statistical code will be made available on Open Science Framework.

Dissemination. The findings are presented in the form of peer-reviewed journal articles and industry reports and presented at scientific conferences. The authors of this protocol will author publications arising from this trial. Media releases and public statements about the research are also made to disseminate the findings to the general public. The findings are also made available to participants if requested. Contact details and procedure for requesting the results are made available in the study information sheet. Trial materials are made available on Open Science Framework following publication of the results.

Discussion

The purpose of the current project is to evaluate the effectiveness of a theory-based intervention using implementation imagery to change drivers' intentions to drive into floodwaters. The intervention will be delivered online using a survey tool containing a series of

infographic videos that present intervention messages. Participants will be randomised to an intervention condition or a control condition. The videos presented to participants assigned to the intervention condition will comprise a series of educational messages about the risks of driving into floodwater and an exercise using implementation imagery. The videos presented to participants assigned to the control condition will comprise the education messages only. The primary outcome variable will be intentions to drive into floodwater, and secondary outcomes will be theory-based constructs identified as important determinants of intentions to drive into floodwater in our previous research (provide references).

Driving into floodwaters is a high-risk behaviour that can be fatal. Reducing drownings from risky aquatic activities during floods has been identified as a priority in the Australian Water Safety Strategy 2016-2020 [12]. Strategies that change drivers' behaviour around floodwater should be at the forefront of efforts to reduce drivers' propensity to drive into floodwaters. The present intervention examines whether a behavioural intervention will be effective in changing driver's intentions drive into floodwater. The intervention has been developed with a focus on effectiveness and potential feasibility. In terms of effectiveness, the intervention is based on psychological theories of attitudes, motivation and decision making, consistent with research indicating that effective behaviour change necessitates a fundamental understanding of behaviour, and that theory-based interventions can lead to more effective and efficient interventions. The intervention content is based on formative research identifying the determinants of risky behaviour when driving in floods and into floodwaters and is designed to target change in behaviour through change in those determinants. In terms of feasibility, the intervention has been designed to be delivered online and uses accessible infographic videos co-designed by researchers and stakeholders. The exercises contained in the videos are designed to be brief and cost-effective, reducing response burden, and maximising the likelihood of engagement. If found to be effective, translation of the intervention into practice will be facilitated by these design features. The brief, online design means it could be

incorporated in websites and disseminated through programs such as learner driver education and during media campaigns during floods with minimal requirement for modification and at relatively low cost. It also paves the way for larger scale usability and feasibility trials.

The intervention will also make a contribution to theory. The current intervention adopts behaviour change strategies that target key theoretical determinants demonstrated to be related to risky driving behaviours around floodwater (reference our and others work). We expect our test of the intervention to contribute to the evidence base of effective methods for changing behaviour. Such evidence is important in order to identify the components of behaviour change interventions that are effective in promoting behaviour change and contributes to more effective and optimally efficient interventions.

A key strength of the study is that it uses a sample with key demographic characteristics proportional to the Australian population, ensuring results are generalisable. While the outcomes are an extensive range of psychological variables established to predict driving into floodwater, the unpredictable and infrequent occurrence of flood events means that examining the effect of our intervention on actual behaviour is not feasible within the timeframe of the study. The paucity of high-quality theory-based intervention research is not unique to driving into floodwater. For example, for another behaviour that carries high risk of drowning, alcohol use during aquatic activities, there has not been any intervention research in more than two decades [39]. If effective, this type of intervention and mode of delivery may be developed and applied to other water safety behaviours with the potential to reduce drowning.

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Ethics approval The study protocol was approved by the Griffith University Human Research Ethics Committee (GU ref no: 2017/895).

Data sharing statement Data will be available following publication of the results at osf.io/z7xph/

Table 1

Behaviour change methods, targeted theoretical constructs, and implementation strategies.

Part	Behaviour change method/s	Implementation strategy	Target construct
1: Education	Information provision	Provide information about the risks of driving into floodwater	Attitudes, risk perception, perceived severity, perceived susceptibility
2: Promoting willingness to form a goal	Personalise risk Scenario-based risk information Provide opportunities for social comparison Goal setting	Providing information about the personal risk; providing reasons people commonly drive into floodwater from prior studies; providing a strategy for overcoming barriers to avoiding driving into floodwater	Intention, attitudes, subjective norm, perceived behavioural control, risk perception, perceived severity, perceived susceptibility, anticipated regret, barrier self-efficacy
3: Practice imagery exercise	Guided practice (imagery skill)	Tangy lemon guided imagery task	Not applicable
4: Process mental simulation	Implementation intentions Goal setting Planning coping responses Guided practice Using imagery	Provide examples of things to do when floodwater is encountered; imagining the steps to use when encountering floodwater while driving; process mental simulation exercise	Intention, perceived behavioural control, barrier self-efficacy, action planning
5: Outcome mental simulation	Personalise risk Information about others' approval Provide contingent rewards Using imagery	Encouragement to think about the things that can happen when driving into floodwater and when avoiding driving into floodwater, including the risk and the benefits. Information about what important others will think; outcome mental simulation exercise	Intention, attitudes, subjective norm, perceived behavioural control, risk perception, perceived severity, perceived susceptibility, anticipated regret
6: Conclusion	Cue altering	Instructing that if ever in the situation to remember goal	Barrier self-efficacy

Note: Part 3 refers to the practice task which is designed to build imagery ability and does not relate to a target construct being assessed.
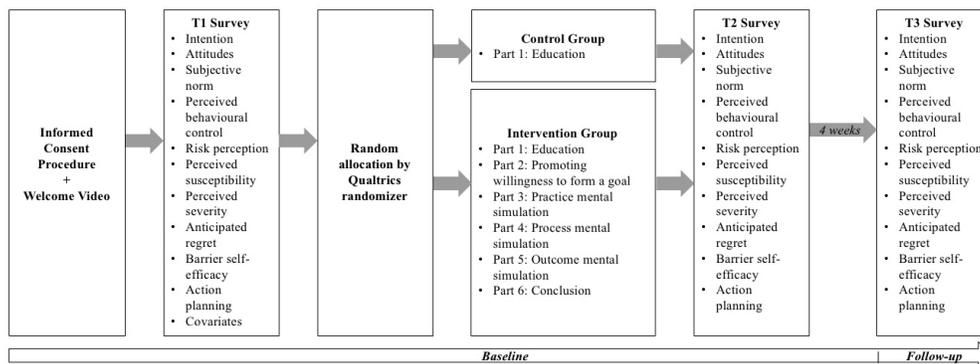
Figure 1. Randomised controlled trial design and participant progression through the study.

462x172mm (72 x 72 DPI)

1

Supplementary Material A – Mental Imagery Video Scripts

Note: The intervention group receives all of the below material. The control group receives the material indicated*. Italicised text is displayed on screen in addition to being read aloud.

*Welcome to the Study Video**

Audio	Video
Welcome to the study. Now that you have read through the study information and agreed to participate, I'd like to quickly recap what participating in the study today will involve. *First, there is a short survey for you to complete on the computer.* Then, *I will* be back to *guide you through some video exercises. Finally, I will leave you with another short survey to complete on the computer.* *Please now click to progress to the next page where the survey will begin.*	Neutral grey

Introduction to Activity Video

Intervention Group Audio	Control Group Audio*	Video
Thank you for answering those questions. For the next 10 or so minutes, I am going to guide you through a video.	Thank you for answering those questions. I am going to guide you through a video.	Neutral grey
In the video, I am going to provide you with some information about driving during flood events.	In the video, I am going to provide you with some information about driving during flood events.	
I am then going to guide you through some mental imagery exercises. In the exercises. In the exercises I will ask you to visualise several scenes in your mind.		
We will begin with a general imagery exercise to get you used to the idea and how it feels, and we will then turn to some exercises related to avoiding driving into floodwater.		
Before we start, I would like you to make yourself comfortable and to make sure you are free from distractions. When you are comfortable and ready to begin, please click to play the next video.	Before we start, I would like you to make yourself comfortable and to make sure you are free from distractions. When you are comfortable and ready to begin, please click to play the next video.	

2

Part 1: Education*

Audio	Video
Between 2002 and 2015, 89 drowning deaths occurred as a result of driving into floodwaters.	Neutral grey
Any flooded road can be deadly. Just a small amount of floodwater can wash your vehicle away.	
The second you decide to push through floodwater, you will give up control.	
The size of your vehicle doesn't matter, nor whether you've driven the road a hundred times before.	
No one can predict what lies underneath the surface. Even gently-moving floodwater can wash away the road surface beneath.	

Part 2: Promoting Willingness to Form a Goal

Audio	Video
Driving into floodwater can affect anyone, including you. So, I would now like you to consider the potential for this to affect you.	Scenes from flood events
People are often tempted to drive into floodwater… *To get home* *To get to work* *Because the other road takes longer* *Because they've done it before* *Because their 4wd can handle it* *Because others are driving through* *Because they think they can assess the risk and manage it*	
But, it is incredibly risky.	
Driving into floodwaters puts you and your passengers at risk and it could be fatal.	
So, what I'd like you to consider today, is forming a goal to avoid driving into floodwater if you encounter it on your route.	
By considering the risks and thinking of a plan, you can avoid driving into floodwater. The best way to get started is to set a goal to avoid driving into any floodwater. You should aim to avoid driving into any floodwater. The mental imagery exercise will help you to achieve your goal.	
On the next page, there is a question to answer. Once you have answered the question, please proceed to the next page and play the video.	

3

Part 3: Practice Imagery Exercise

Audio	Video
We will now begin a general exercise to get you used to the idea of mental imagery and how it feels. When doing mental imagery, people often find it useful to close their eyes. So now, let's begin. The first exercise is to prepare you for the mental imagery exercise ahead. The idea is for you to just relax and visualise the images as I talk you through it. So, imagine this scene. You are in your kitchen. In front of you there is a chopping board and a sharp knife. On the chopping board is a large, round, ripe, bright yellow lemon. Look closely at the lemon. *[5 second pause]* Pick up the lemon. Feel the lightly pitted texture of the peel, the vividness of the yellow of its colour, and the strong, tangy lemon smell. You rub the lemon gently with your fingers, and that causes the smell to grow stronger. The smell transfers to your fingers as you rub it. Hold it up to the light and look at it for a moment. Notice its colour and texture. *[5 second pause]* Now, put the lemon back on the chopping board. Pick up the knife and imagine yourself cutting the lemon down the middle. Feel the pressure of the knife handle on your hand as you cut into the lemon. See the juice burst out of the lemon, and cascade on to the board. Smell the intensity of the smell of the lemon juice. *[5 second pause]* Ok, pause there. You can open your eyes, but just stay relaxed. That completes the first exercise. The idea was to get you used to imagining a scene with great intensity and to familiarise you with how to use imagery. Often imagery is quite challenging for people. The idea is to actually feel as if you are there, 'in the moment', and to use all of your senses.	Lemon image

4

Part 4: Process Mental Simulation

Audio	Video
Now that you have practiced using mental imagery, I want you to use those skills in the following task, which will also require some imagery. The next exercise will help you to achieve your goal of avoiding driving into floodwater. Here are some examples of things you may do when you encounter floodwater: - *You could stop, and remind yourself that driving into floodwater is too risky. You could not worry about other cars that are waiting, or about how much you need to get to your destination.* - *You could pull to the side of the road and plan an alternative route.* - *And then you could turn around and follow your alternative route.* Now I would like you to go on to the next imagery exercise. [rain audio begins] Research has shown that you are more likely to actually carry out this intention if you 'mentally image' performing the intention in a very vivid manner, using your senses and imagination to make the imagery as realistic as possible. You will find that it might help to close your eyes when doing your imagery. If you wish, you can do so now.	Neutral grey
Now, please spend 2-3 minutes, imagining some steps you could use to avoid driving into floodwater. Think about a scenario where you are driving in your car immediately after a thunderstorm. You approach a section of the road that is completely covered in water. Think about all the things you would need to do in order to achieve your goal and think about all the things you would need to overcome.	Car at night in rain approaching floodwater
I will let you know when a few minutes have passed.	Black
[Visualisation exercise – 2-minute pause]	
[rain audio ends] Alright, now that you have finished your imagery, please note down in the space below a few sentences summarising the things you imagined you need to do to avoid driving into floodwater. It should be as detailed as possible. Writing down your images helps you to remember them more vividly. Spend about 2 to 3 minutes writing down your thoughts.	Neutral grey

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Part 5: Outcome Mental Simulation

Audio	Video
Please again make yourself comfortable and make sure that you are free from distractions. I am now going to guide you through some more imagery. Again, you may find it helpful to close your eyes. *[5 second pause]*	Car at night in rain approaching floodwater
Now think about the potential things that could happen if you drive into floodwater. *[10 second pause]*	Black
Now think about some of the outcomes if you avoid driving into floodwater. For example: It took a little bit longer, but you made it home safely. *[10 second pause]*	Car at night in rain approaching floodwater
	Black
Now, think about your goal to not drive into any floodwater. Now close your eyes again and imagine yourself having achieved that goal. *[10 second pause]*	Car at night in rain approaching floodwater
Think of all the effort you put in to achieving your goal now that you have finally accomplished it. Imagine the result of accomplishing this goal. *[10 second pause]* Think about all of the benefits you will gain: your safety and your passenger's safety; not suffering the expense of wrecking your car. Try to feel the satisfaction you would have with this accomplishment. Imagine a typical flood event and see yourself as someone who does not drive into floodwater. *[10 second pause]* Now, think about your loved ones, your family, children, and friends. What will they think if you achieved your goal to not drive into any floodwater? *[10 second pause]* Now you have finished your imagery, using the space below, please note down a few sentences summarising the positive benefits you imagined as a result of not driving into floodwater. It should be as detailed as possible. Spend about 2-3 minutes writing down your thoughts.	

6

Part 6: Conclusion

Audio	Video
Thank you for your attention, and if you're ever in the situation, please remember your goal. Please now proceed to the next page which contains some more questions for you to answer.	Neutral grey

Supplementary Material B

Items and response scales for measurement of psychological constructs

Behaviour	Definition
Driving through floodwater[a]	The following questions will ask about your knowledge and attitudes towards driving through floodwater. "Floodwater" refers to a body of water covering land that is normally dry. For the next questions, please think about your driving through floodwater. For example, think about the scenario where you are driving in your car immediately after a thunderstorm. You approach a section of the road that is completely covered in water. Now consider your future driving, if such a scenario occurred, how likely are you in the future to drive through the floodwater…?".
Avoiding driving through floodwater[b]	The following questions will ask about your knowledge and attitudes towards driving through floodwater. "Floodwater" refers to a body of water covering land that is normally dry. For the next questions, please think about your driving through floodwater. For example, think about the scenario where you are driving in your car immediately after a thunderstorm. You approach a section of the road that is completely covered in water. Now consider your future driving, if such a scenario occurred, how likely are you in the future to AVOID driving through the floodwater…?".

Construct	Items	Scoring
Intention[a]	I intend to drive through the floodwater. I expect I would drive through the floodwater. It is likely that I will drive through the floodwater. In general, I would be willing to drive through the floodwater.	[1] extremely unlikely – [7] extremely likely
Attitudes[a]	If I were to drive through the floodwater, it would be…	[1] bad – [7] good [1] harmful – [7] harmless [1] unwise – [7] wise [1] intelligent – [7] stupid [1] negative – [7] positive
Subjective Norm[a]	Most people who are important to me would approve of me driving through the floodwater. Those people who are important to me think that I should drive through the floodwater. Those people who are important to me would want me to drive through the floodwater.	[1] strongly disagree – [7] strongly agree

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	Those people who are similar to me would drive through the floodwater.	
	Most people like me would drive through the floodwater.	
Perceived Behavioural Control[a]	It is mostly up to me whether I drive through the floodwater. I have complete control over whether I drive through the floodwater. It would be easy for me to drive through the floodwater. I am confident I could drive through the floodwater.	[1] strongly disagree – [7] strongly agree
Risk perception[a]	It would be risky for me to drive through the floodwater. If I drive through the floodwater there would be risk involved.	[1] strongly disagree – [7] strongly agree
Perceived susceptibility[a]	My chances of having trouble if I drive through the floodwater are great. There is a good possibility that I will have trouble if I drive through the floodwater. I would be worried about having trouble if I drove through the floodwater.	[1] extremely unsusceptible – [7] extremely susceptible
Perceived severity[a]	If I drive through the floodwater, the consequences would be…? If you drive through the floodwater, to what extent would it impact severely on your life?	[1] not at all severe – [7] extremely severe
Anticipated regret[a]	If I were to drive through the floodwater, I would feel regret. If I were to drive through the floodwater, I would feel sorry for doing it. I would feel upset if I drove through the floodwater.	[1] strongly disagree – [7] strongly agree
Barrier self-efficacy[b]	I am confident I can avoid driving through floodwaters in the future…? … even when I might be late for work … even when I need to get to my children/other family members … even when I need to get home to check on the house/pets etc … even when the alternative route will take more time/is inconvenient … even when I see others driving through … even when I think I can make it … even when I feel pressure from others to drive through … even when I know others are around to help if something goes wrong … even when I think my vehicle is capable to drive through	[1] not at all confident – [7] definitely confident
Action planning[b]	Do you have a plan with regard to AVOIDING driving through floodwater next time you encounter it on your route? When to avoid driving through floodwater Where to avoid driving through floodwater How to avoid driving through floodwater How often to avoid driving through floodwater	[1] not at all true – [7] exactly true

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Imagery ability[c]	Typically, I… Have a rich vocabulary Have difficulty understanding abstract ideas Have a vivid imagination Am not interested in abstract ideas Have excellent ideas Do not have a good imagination Am quick to understand things Use difficult words Spend time reflecting on things Am full of ideas	[1] very inaccurate – [5] very accurate
Willingness to form a goal[c]	Now that you have heard some information about driving into floodwater, please indicate your agreement with the following statement: I am willing to form a goal to avoid driving through floodwater	[1] strongly disagree – [7] strongly agree
Imagery fidelity[d]	Vividness: How VIVID was the mental image that you had of yourself avoiding driving through the floodwater? Clarity: How CLEAR was the mental image that you had of yourself avoiding driving through the floodwater? Detail: How DETAILED were the images that you had of yourself avoiding driving through the floodwater? Ease: How easy or difficult was it for you to create these images?	[1] not at all vivid – [7] very vivid [1] not at all clear – [7] very clear [1] not at all detailed – [7] very detailed [1] extremely easy – [7] extremely difficult

Note: [c]covariate; [d]intervention group only

10

Supplementary Material C – Informed Consent Materials

Investigating Driver Behaviour During Floods

INFORMATION SHEET

Chief Investigator	Co-Investigator
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Why is the research being conducted?

The aim of the current study is to develop an understanding of driver behaviour during floods. The research team requests your assistance in helping us with this research.

What you will be asked to do

Your participation in this project will involve completing a brief online survey that will ask questions about your knowledge and attitudes toward driving through floodwater. You will also be asked to provide some background demographic details. This information is not used to identify you in any way but rather it will tell us about the representation of the individuals participating in the study. In addition, you will be required to watch a short 5-minute video and then fill in another online survey. The study will take approximately 35 minutes to complete. One week and four weeks after completing these tasks we will contact you by email and ask you to complete another short questionnaire, which will take approximately 15 minutes. These videos will require sound and you will need to be in a place that is quiet and free from distractions. You may prefer to use headphones to reduce distractions from background noise. The survey has been optimised for computer delivery and may not work properly on smartphones.

Participant selection and/or screening

We welcome your participation if you have are an Australian resident with a registered driver's licence.

The expected benefits of the research

It is expected that this project will not directly benefit you. However, your involvement will provide valuable information about decisions regarding driving through floodwater and, therefore, may benefit others through a greater understanding of these processes.

Risks to you

It is unlikely that there are any risks greater than daily living involved with participation in this project. However, should you experience any discomfort due to undertaking this survey, Lifeline (13 11 14) offers a free 24 hour telephone counselling service.

Your participation is voluntary

Your participation in this project is completely voluntary and you may cease participation at any time. If you agree to participate, you can withdraw from participation at any time during the project without comment or penalty. However, once your responses have been submitted and we have de-identified them, you will be unable to withdraw. Your decision to participate will in no way impact upon your current or future relationship with Griffith University.

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Your confidentiality

The information you provide will be treated confidentially and all comments and responses are anonymous. Please do not put your name on the questionnaire. Your responses to the questionnaire will form part of a large data response set, which will initially be stored by Qualtrics. Research data from Qualtrics will be downloaded and stored securely on Griffith University's Google Drive or OneDrive allocation. Data will be password-protected and accessible only to members of the research team. As required by Griffith University, all research data (survey responses and analysis) will be retained in a password-protected electronic file for a minimum period of five years before being destroyed. Participants will be given the opportunity separately to express consent to be contacted for the follow-up survey. These contact details will be deleted following conclusion of the follow-up survey. A personal code identifier will be used to match surveys. Participants' data will not be identifiable in any publication or reporting. In the interest of researcher transparency, a strictly de-identified version of the research data will be prepared and made available on the online open data repository Open Science Framework (https://osf.io/).

Consent to participate

Completion and submission of the survey will be accepted as informed consent to participate.

Questions / further information about the project

Please contact the research team members if you have any questions or require further information about the project.

Feedback to you

No automatic feedback will be given to you about the results of this study. However, if you participate and wish to receive a summary of the research results once the study has been completed, you can email the research team members.

The ethical conduct of project

Griffith University conducts research in accordance with the *National Statement on Ethical Conduct in Human Research*. If you do have any concerns or complaints about the ethical conduct of the project you may contact the Manager, Research Ethics on (07) 3735 4375 or research-ethics@griffith.edu.au. This project has received ethical approval from the Griffith University Human Research Ethics Committee (GU Ref no: 2017/895).

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	#3	Date and version identifier	N/A
Funding	#4	Sources and types of financial, material, and other support	22
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	22
Roles and responsibilities:	#5b	Name and contact information for the trial sponsor	22

sponsor contact information			
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	22
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-6
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	10
Objectives	#7	Specific objectives or hypotheses	5-6
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	7
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7-8
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-10

Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	N/A
Interventions: adherence	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	8
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10-13
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	13
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	7-8
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8
Allocation concealment	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed	8

mechanism		envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7-8
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	7-8
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	8
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	15-16
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14

Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	16
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	14
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	15
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	15
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	15
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	15
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	15
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	22
Data access	#29	Statement of who will have access to the final trial dataset,	15-16

			and disclosure of contractual agreements that limit such access for investigators	
Ancillary and post trial care	#30		Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	15
Dissemination policy: trial results	#31a		Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	16
Dissemination policy: authorship	#31b		Authorship eligibility guidelines and any intended use of professional writers	16
Dissemination policy: reproducible research	#31c		Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	16 & 22
Informed consent materials	#32		Model consent form and other related documentation given to participants and authorised surrogates	Supp C
Biological specimens	#33		Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

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BMJ Open

A protocol for developing a mental imagery intervention: A randomised controlled trial testing a novel implementation imagery e-health intervention to change driver behaviour during floods

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Manuscripts

Running head: FLOODWATER DRIVING IMAGERY INTERVENTION PROTOCOL   1

A protocol for developing a mental imagery intervention: A randomised controlled trial

testing a novel implementation imagery e-health intervention to change driver behaviour

during floods

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Journal: BMJ Open

Type of Contribution: Research protocol

Abstract

Introduction: Drowning due to driving into floodwater accounts for a significant proportion of all deaths by drowning. Despite awareness campaigns such as 'If it's flooded, forget it', people continue to drive into floodwater. This causes loss of life, risk to rescuers, and damage to vehicles. The aim of this study was to develop and evaluate an online e-health intervention to promote safe driving behaviour during flood events.

Methods and analysis: The study will utilise a 2x3 randomised controlled trial in which participants are randomised into one of two conditions: (1) education about the risks of driving into floodwater; or, (2) education about the risks of driving into floodwater plus a theory-based behaviour change intervention using planning and imagery exercises. The effect of the intervention on the primary outcome, intention to drive through floodwater, and the secondary outcomes, will be assessed using a series of mixed-model ANCOVAs.

Ethics and dissemination: The study has been approved by the Griffith University Human Research Ethics Committee. Participants will review a study information sheet and provide informed consent prior to commencing participation. Results will be disseminated through peer-reviewed publications, industry reports, media releases, and at academic conferences. Deidentified data will be made publicly available following publication of the results.

Trial Registration: ACTRN12618001212246
Available at: http://www.ANZCTR.org.au/ACTRN12618001212246.aspx

Keywords: Flooded waterways; social cognitive theories; driving; drowning, water safety; mental imagery

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Article Summary
- The study intervention is theory-based, consisting of a novel integration of effective behaviour change strategies.
- The study will use a sample with key demographic characteristics proportional to the distribution of flood-related transport deaths in the Australian population, ensuring that the results are generalisable.
- While the outcomes are an extensive range of psychological variables established to predict driving into floodwater, the unpredictable occurrence of flood events means that examining the effect of our intervention on actual behaviour is not feasible within the timeframe of the study.

Introduction

Drowning is the third leading cause of injury-related deaths worldwide [1] and the leading cause of death during times of flood [2][3]. Activities such as driving into, walking near, or engaging in recreational activities near or in floodwater are commonly reported as preceding drowning [1]. Reports have shown that, in Australia, around 53% of flood-related deaths and 55% of all river flood-related unintentional fatal deaths [4] were the result of driving into floodwaters. Another recent study surveyed more than 600 Australian river users and found 35.7% of participants reported having driven into floodwater, with males (43.9%) significantly more likely to have driven into floodwaters than females (27.8%) [5]. These drowning statistics also likely underestimate the true extent of the driving-related drownings due to limitations around the use of International Classification of Diseases (ICD) flood-related drowning codes [6][7].

Due to the magnitude of this issue, intentionally driving into floodwater has been the subject of mass-media drowning prevention campaigns such as 'Turn Around Don't Drown' [8] in the United States and 'If it's flooded, forget it' [9] in Australia. However, very little research to date has evaluated the effect of these campaigns on attitudes, motivation, and actual drowning rates. In fact, fatal and non-fatal drownings resulting from intentionally driving into floodwater continue to occur regularly [10-12]. For example, during a severe weather event in a 24-hour period, in March 2017, 108 floodwater rescues were conducted in Queensland, Australia by the State Emergency Service [13]. This has in resulted in a national call for research into behaviours around floodwater [12].

In response to a paucity of empirical research, we conducted a series of studies to understand the psychological processes underpinning decisions around driving into floodwater [14-16], avoiding driving into floodwater [17], and the experiences of those who rescue drivers who have driven into floodwater [18]. While it is commonly assumed that people choose to drive into floodwater due to a lack of awareness of the risks, our research identified that many of the

people who drive into floodwater are aware of the risks and have been exposed to relevant mass-media campaigns [14].

Building on this research, we developed and evaluated a mass-media style infographic video that included theory-based behaviour change methods to bridge the gap between awareness and intentions to drive into floodwater [19]. While the video had an effect on attitudes, subjective norm, perceived susceptibility, and perceived severity immediately post-intervention, these effects were only maintained at the four-week follow up for women and not men. Further, there was no effect of the video on intentions [19]. Therefore, continued development and evaluation of interventions aimed at promoting safe driving behaviour during floods is a priority. Some potential explanations for the null effect of the infographic on intentions are that the intervention did not directly target intentions and/or did not aid in the development of a plan that can be implemented if this particular situation arises for the person during a flood event (i.e. faced with a flooded road whilst in their vehicle). We also suspect that gender differences in the effects at follow-up may have been due to females self-reinforcing the messages contained within the intervention due to a greater tendency to utilise ruminative thinking styles [20]. This suggests that an effective intervention aimed at promoting safe driving behaviour during floods should utilise behaviour change methods that aid in the development of a plan and when to implement it, such as implementation intentions [21]; and, allow sufficient internalisation of the intervention content through strategies such as mental imagery [22].

Implementation intentions are concrete plans about when, where, and how to enact a behaviour to achieve a specific goal which contrasts from simply intending to achieve a goal–otherwise known as goal intentions [23]. Implementation intentions have been found to be superior to goal intentions in achieving goals, with a meta-analysis finding medium to large effects of implementation intentions on goal achievement [24]. Conroy and Hagger [22] describe mental imagery interventions as involving "self-directed imagining or visualizing specific

events, actions, or outcomes, including concomitant feelings and responses, with the express

purpose of increasing motivation toward a target action or task" (p. 669). Conroy and Hagger's

(2018) meta-analysis of imagery interventions in health behaviour found nontrivial small

averaged corrected effects of these interventions on post-intervention behaviours, intentions,

perceived control, and attitudes; and, identified characteristics of interventions that moderate

the effect size. A small number of studies have combined implementation intentions and

mental imagery to change health behaviours such as fruit and vegetable consumption [25] and

alcohol intake [26] yielding small to medium effect sizes. In building upon our prior work [19], we

therefore seek to combine two behaviour change strategies–mental imagery and

implementation intentions–to develop an *implementation imagery* intervention to promote less

favourable intentions to drive into floodwater. Implementation imagery is an intervention

procedure comprising imagery and planning exercises. Participants are prompted to imagine

the steps required to engage in a future motivated behaviour and form a concrete plan to

implement the steps. We propose a six-part implementation imagery intervention procedure for

the proposed intervention aimed at avoiding driving into floodwater. In Part 1, participants will

be provided with information on the target behaviour. In Part 2, participants will receive a

persuasive communication prompting participants to form a goal to perform the target

behaviour in the future. In Part 3, participants will be asked to complete a practice imagery

exercise. In Part 4 respondents will be instructed to imagine the steps required for them to

achieve the goal set in Part 2 and develop and specify a plan to follow the steps if they were to

encounter floodwater while driving. In Part 5, participants will be prompted to imagine the

outcomes associated with enacting the plan to highlight the personal relevance of the plan. In

Part 6, participants will be provided with a final statement indicating when they should

remember their plan.

Objectives

Drawing on our previous research [14-19] we aim to develop a theory-based behavioural

intervention to promote less favourable intentions of drivers to drive into floodwaters. The

research will be conducted in two phases, a development phase in which the theory-based

content of the implementation imagery intervention embedded in a survey will be developed

and piloted, and an implementation and evaluation phase in which the effect of the intervention

in changing intentions and beliefs with respect to driving into floodwaters, will be tested in a

population of drivers using a randomised controlled design. Drivers recruited to the trial are

randomly assigned to intervention or control conditions. Participants assigned to the

implementation imagery condition receive a set of education-based messages that focus on

changing attitudes and intentions with respect to driving into floodwaters, and the theory-based

implementation imagery exercises. The control condition receives the education-based

messages alone, which are drawn from information commonly disseminated by public safety

organisations. This represents a "usual care" control condition. Specifically, the objectives of

the current study are to: (a) test the effectiveness of the intervention administered after baseline

measures of study constructs at Time 1 (T1) in changing drivers' intentions and beliefs

immediately post-intervention at Time 2 (T2); (b) determine whether the effects of the

intervention are maintained four weeks later at Time 3 (T3); compare the effects of the

intervention to effects of a comparison condition comprising publicly available education on

driving into floodwater; and, (d) examine gender differences in intervention effects at T2 and

T3.

We hypothesise that drivers assigned to the intervention condition will report

significantly lower intentions to drive through floodwater, relative to the control condition

immediately post-intervention at T2 (primary outcome; Hypothesis 1). With regard to the

secondary outcomes, we hypothesise that drivers assigned to the intervention condition will

report significantly less favourable attitudes and reduced perceived social pressure to drive

through floodwater, as well as greater perceptions of behavioural control, risk perception, perceived susceptibility, perceived severity, and anticipated regret toward driving through floodwater, relative to the control condition immediately post-intervention at T2 (Hypothesis 2). We further hypothesise that that drivers assigned to the intervention condition will report significantly greater barrier self-efficacy and action planning regarding avoiding driving through floodwater, relative to the control condition immediately post-intervention at T2 (Hypothesis 3). We also expect that the effects of the intervention will be maintained four-weeks later at T3 (Hypothesis 4). Given our previous research has identified gender differences in changing beliefs [19], we will also test for sex differences in the effects of the intervention on study outcomes.

Methods and Analysis

The study protocol is reported in accordance with SPIRIT Statement standard protocol items for clinical trials [27] [28].

Intervention Development and Optimisation

The intervention content was developed based on existing safety messages [9], our prior research [14] [17], behaviour change methods [29], and best-practice techniques for implementation intentions and mental imagery [22]. Prior to recording, the scripts were reviewed by a panel of experts in drowning prevention, behaviour change, and media and communication. The scripts were also piloted with two Australian drivers and feedback was invited. Based on initial expert and driver feedback, refinements to wording of the scripts were made. The scripts were then audio-recorded using a voiceover actor and developed into videos. The videos then underwent further expert review and piloting with seven drivers from the target population. The pilot involved the participants completing the T1 survey, the intervention, the T2 survey, and then a semi-structured interview where they were asked broadly about their thoughts regarding the exercises. The participants were probed for specific information regarding clarity and timing of the different exercises in the video if it was not already shared. The drivers were purposively

recruited to ensure a range on key demographic factors of age, sex, and education level. Based

on qualitative feedback provided by pilot participants, we made data-driven refinements to the

presentation and timing allocated to the exercises.

Patient and Public Involvement

Patient and public involvement in the development of the intervention was conducted

through our prior research which involved qualitative interviews with members of the target

population [14 17]—Australian drivers—and through piloting of the intervention materials with

Australian drivers. Specifically, drivers' descriptions of the behaviour informed the wording

of the items used in the outcome measures. Drivers' descriptions from these studies also

informed the content of the intervention. The research questions were developed around

evaluating the effect of the intervention on psychological constructs that have been found to

predict willingness to drive through floodwater in prior research [15 16]. Drivers will not be

involved in the recruitment or conduct of the study. Participants will be provided with the

contact details of the research team on the study information sheet and will be informed that

they can contact the research team if they wish to receive the results of the study. The burden

of participating will be assessed by the drivers after having read the study information and

prior to provision of informed consent.

Study Design

The intervention will be evaluated against the control condition immediately post-

intervention (T2) and four-weeks later (T3). The evaluation will adopt a 2 (intervention

condition: education and implementation intention imagery condition vs. education only

condition) x 3 (time: T1, T2, T3) parallel group randomised controlled design. Figure 1

illustrates the design of the intervention and participant flow through the study.

INSERT FIGURE 1 HERE

Setting and Participant Recruitment

The randomised controlled trial will be conducted using an online survey tool (Qualtrics[TM]). Participants will be eligible if they hold a valid full driver's licence, are an Australian resident, and are the only member of their household participating in the study. Participants will be recruited using a research panel provider and screened by the provider before entering the trial. In addition to the inclusion criteria, participants will be screened on the following demographic characteristics and quotas will be imposed to ensure that the sample comprises similar proportions of these characteristics to the distribution of flood-related transport deaths in the general population: age, sex, geographic region (by state and metropolitan vs. rural), and household income. The study will adopt a double-blind procedure. Participants will be unaware of the condition to which they have been assigned and study purpose. Staff at the research panel company who may have direct contact with the participants will also be unaware of the conditions and purpose of the study.

Data Quality

Two questions will be embedded within the T1 survey to assess attentive responding [30] [31]. The questions instruct the choice of a particular answer so that it is not possible to answer the question incorrectly if the item is read carefully (e.g., "please choose option two to ensure you are paying attention"). Participants who do not answer both of the items correctly will be excluded.

Randomisation

Randomisation into one of the two groups will be conducted by the Qualtrics randomizer feature following the T1 survey. The Qualtrics randomizer operates using a Mersenne Twister pseudorandom number generator. The Mersenne Twister is the default pseudorandom number generator for a range of widely used software packages including Microsoft Excel and SPSS. By nature of this method of random assignment, the sequence cannot be determined until the participant is assigned.

Intervention Condition

Participants will be initially presented with a brief information sheet outlining study expectations and participant rights prior to completing an informed consent form. They will then watch a brief 'welcome' video to familiarise participants with the voice of the narrator, and to give participants the opportunity to enable the audio on their device prior to commencing the intervention. Next, participants will complete the T1 (pre-intervention) questionnaire, after which they will be randomised into one of two conditions (see Figure 1 for trial design). Both groups will watch the welcome video; however, the welcome video for the control group does not make reference the mental imagery activity. The intervention group will receive the following six-part procedure, while the control group will receive only Part 1. Participants are then directed to the T2 survey. See Supplementary Material A for video scripts. The intervention is structured such that participants receive information, then form a goal intention, and then go on to make a plan. After imagining their plan and noting it down, participants are instructed to imagine the outcomes associated with enacting their plan to highlight personal relevance. The intervention utilises a range of behaviour change methods [29], which have been mapped on to theoretical constructs that comprise the study outcomes (see Table 1).

Part 1: Education. The first video is designed to educate participants on the risks of driving into floodwater. It has been composed based on information that is publicly available and commonly broadcasted in Australia.

Part 2: Formation of a goal intention. The second video is designed to encourage participants to form a goal intention to avoid driving into floodwater if they encounter it on their route and to indicate that by forming a plan of what do in this situation, they can achieve their goal and avoid driving into floodwater. The video contains visuals of rain, floodwater, and a floodwater damaged road, and drivers are provided with further information about why people driver into floodwater drawn from our prior research [14 17]. Following Part 2, participants

will complete a single-item measure of goal intention, indicating their commitment to the goal (See Supplementary Material B for question details).

Part 3: Practice imagery exercise. Prior to the process imagery exercise, participants are provided with a practice guided imagery exercise. The purpose of the exercise is to allow participants to familiarise them with the practice of imagery, and to get them to relax and begin visualising vivid images. The practice guided imagery exercise prompts participants to imaging cutting into a lemon with a knife. The exercise uses a familiar situation in order to facilitate imagery.

Part 4: Process imagery exercise. Following the practice exercise, participants are provided with some examples of safe options to take should they encounter floodwater on their route. Participants are then instructed to imagine approaching floodwaters while driving their car and consider the steps they could take to avoid driving into the floodwater. Participants are then instructed to visualise these scenes independently for approximately two minutes. After the exercise is complete, the narrator advises the participant that the activity is over and requests that they note down the plan that they imagined in a response box below the video.

Part 5: Outcome imagery exercise. Participants watch a video which guides them through an outcome imagery exercise. This involves imagining the outcomes that may occur if they drive into floodwater, followed by a range of outcomes that would occur if they do not drive into floodwater. After the exercise is complete, the narrator advises the participant that the activity is over and requests that they note down the things they imagined in the space below the video.

Part 6: Conclusion. Following the final imagery exercise, participants watch a video thanking them for their attention and reminding them that if they are ever in the imagined situation, to remember their goal. The purpose of this is to create a cue that may be triggered by a situation similar to that imagined during the intervention.

Running head: FLOODWATER DRIVING IMAGERY INTERVENTION PROTOCOL   12

Imagery fidelity. Fidelity of the imagery intervention will be assessed using four items modified from Knäuper, et al. [25]. The items assess vividness, clarity, detail, and ease of imagery on 7-point scales (e.g., "How CLEAR was the mental image that you had of yourself avoiding driving through the floodwater?"). The 7-point scales vary for each item and are described in Supplementary Material B.

Control Condition

Participants in the control group will receive the Part 1: Education video and will then then be directed to the T2 survey. This active control condition was chosen as the comparator to allow the effect of the imagery intervention to be examined above and beyond the effect of simply providing information about the behaviour.

Outcomes

Psychological measures. Participants will complete measures of psychological constructs from two social-cognitive theories: the theory of planned behaviour [32] and the health action process approach [33]. These theories were selected because they have used to identify the psychological determinants of a range of health and safety behaviours [34][35]. The psychological constructs will be measured on multi-item psychometric instruments developed using standardised guidelines (e.g., Ajzen, 2006 [36])[a]. While we discuss the behaviour in this study as "driving into floodwater" because by nature there is no certainty around a driver making it through, we measure the behaviour using the wording "driving through floodwater". This is based on our prior qualitative work where participants most commonly described the behaviour in this way [14][17]. The self-report psychological measures will be administered at T1, T2 and T3. See Supplementary Material B for all measures used in the study.

Intention. Intention to drive through floodwater will be measured using four items (e.g., "I intend to drive through the floodwater"). Responses are provided on 7-point scales (1 =

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[a] All scales measuring social-cognitive constructs except action planning and perceived behavioural control have been used in our previous study [19], exhibiting good internal consistency.

strongly disagree and 7 = *strongly agree*). Change in intention is the primary outcome in the

study. The following outcomes are secondary outcomes.

     Attitudes. Attitudes towards driving through floodwater will be assessed using five

items preceded by the common stem: "If I were to drive through the floodwater, it would be"

Responses will be provided on semantic differential scales (e.g., 1 = *bad* and 7 = *good*).

     Subjective norm. Subjective norm will be measured using five items prompting

participants to rate the extent to which important others would want them to drive through

floodwater and whether people similar to them would drive through (e.g., "Most people who

are important to me would approve of me driving through the floodwater"). Responses are

provided on 7-point scales (1 = *strongly disagree* and 7 = *strongly agree*).

     Perceived behavioural control. Perceived behavioural control will be measured using

three items assessing drivers' perceptions of their ability to control the behaviour (e.g., "I have

complete control over whether I drive through the floodwater"). Responses are provided on 7-

point scales (1 = *strongly disagree* and 7 = *strongly agree*).

     Risk perception. Risk perception will be measured using a two-item scale (e.g., "It

would be risky for me to drive through the floodwater". Responses are provided on 7-point

scales (1 = *strongly disagree* and 7 = *strongly agree*).

     Perceived susceptibility. Perceived susceptibility will be measured using a three-item

scale (e.g., "My chances of having trouble if I drive through the floodwater are great").

Responses are provided on 7-point scales (1 = *extremely unsusceptible* and 7 = *extremely*

susceptible).

     Perceived severity. Perceived severity will be measured using a two-item scale (e.g., "If

I drive through the floodwater, the consequences would be…"). Responses are provided on 7-

point scales (1 = *not at all severe* and 7 = *extremely severe*).

Anticipated regret. Anticipated regret will be measured using a three-item scale (e.g., "If I were to drive through the floodwater, I would feel regret". Responses are provided on 7-point scales (1 = *strongly disagree* and 7 = *strongly agree*).

Barrier self-efficacy. Barrier self-efficacy will be measured using nine items assessing drivers' confidence to avoid driving through floodwater (e.g., "I am confident I can avoid driving through floodwaters in the future… even when the alternative route will take more time/is inconvenient". Responses are provided on 7-point scales (1 = *strongly disagree* and 7 = *strongly agree*). The barrier self-efficacy items were developed using belief elicitation in our prior work [17] with a sample of drivers who had avoided driving into floodwater when they encountered it on their route.

Action planning. Action planning will be measured on a four-item scale (e.g., "I have made a plan regarding… How to avoid driving through floodwater"). Responses are provided on 7-point scales (1 = *not at all true* and 7 = *exactly true*).

Covariates. Consistent with the approach taken in our prior work [19], a number of demographic variables will be measured and used as covariates in the analyses. Goal intention and imagery ability will also be measured and used as covariates.

Demographic and other background factors. Demographic and background details are collected at T1 including: (i) gender (0 = *male* and 1 = *female*); (ii) age (in years); (iii) relationship status (0 = *not married* and 1 = *married*); (iv) education level (0 = *non-university* and 1 = *university*); (v) number of years driving; (vi) number of children; and (vii) past frequency of driving through floodwater measured using a single item: "How often in the past 5 years have you driven through floodwater? 'Floodwater' refers to a body of water covering land that is normally dry", with responses provided on a 7-point scale (1 = *never* and 7 = *very often*).

Goal intention. Following Parts 1 and 2 of the intervention (or Part 1 for the control group), participants will be asked a question to assess their willingness to form a goal to avoid

driving into floodwater, "Now that you have heard some information about driving into

floodwater, please indicate your agreement with the following statement: I am willing to form

a goal to avoid driving through floodwater", responses provided on a 7-point scale (1 =

strongly disagree and to 7 = *strongly agree*).

Imagery ability. Individual differences in imagery ability will be measured using a 10-

item scale drawn from the International Personality Item Pool (IPIP) [37] and designed to

measure Factor V (Intellect and Imagination) of Goldberg's Big-Five Factor Markers [38].

Responses provided on 5-point scales (1 = *very inaccurate* and 5 = *very accurate*). For

example, "Typically, I… Have a vivid imagination".

Power analysis. An *a priori* power analysis is conducted using G*Power v3.1 for an

ANCOVA model estimating fixed effects, main effects, and interactions. The effect size was

set to f = .25 (corresponding to the effect size of intention from pre- to post-intervention in

Hamilton et al., 2018 [19]) to detect a medium effect, with power set at .95 and alpha set at .01

(adjusted to protect from inflation of type I error rate due to multiple tests). Inclusion of nine

covariates was also specified. The analysis yielded a total minimum required sample size of

289. We aim to recruit 460 participants at the baseline in order to meet our target sample size

of 300 participants at the follow-up (allowing for up to 35% attrition). Recruitment of will

cease when 460 participants have participated in the baseline.

Statistical analysis. Hypotheses will be tested using a series of mixed-model

ANCOVAs. In the analyses, condition/group will be a between-participants variable; Time

(T1, T2, T3) will be a within-participants variable; and the primary outcome (intention) and

secondary outcomes (attitudes, subjective norm, perceived behavioural control, risk perception,

perceived susceptibility, perceived severity, anticipated regret, barrier self-efficacy, action

planning) will be separate dependent variables. Consistent with the approach taken in our prior

work [19], demographic variables (gender, age, relationship status, educational level, number of

years driving, number of children, and past frequency of driving through floodwaters) will be

included as covariates in the analyses. Mental imagery ability and goal intention will also be

included as covariates. Where an ANCOVA indicates that there is a significant time*group

interaction for any of the outcome variables, simple effects analyses using estimated marginal

means will be conducted for that outcome. Specifically, we will compare within-group

differences in the outcome between time points, and between-group differences in the outcome

at each time point. Alpha will be set at .01 for all analyses (adjusted to protect from inflation of

type I error rate due to multiple tests). Missing data will be imputed using the Expectation-

Maximisation (E-M) algorithm.

Ethics and Dissemination

Ethical approval for the study has been granted by the Griffith University Human

Research Ethics Committee (GU ref no: 2017/895). We anticipate that the rigorous

development and piloting process will ensure that no amendments to the protocol are required.

However, if any amendments are required, they will be submitted as amendments to the

Australian New Zealand Clinical Trials Registry record and reported in the final report of the

study. We do not anticipate any risks greater than daily living to be involved with participation

in this project, and no discomfort or adverse effects were reported by participants in the pilot

study. However, participants are provided with the following information: "should you

experience any discomfort due to undertaking this survey, Lifeline (13 11 14) offers a free 24-

hour telephone counselling service".

Informed consent. Before being presented with the online baseline survey, participants

are presented with the study information sheet. The information sheet indicates that proceeding

to the next page and commencing participation will be considered consent to participate.

Participants are also advised in the information sheet that they are free to cease participation at

any time without comment or penalty. See Supplementary Material C for informed consent

materials.

Confidentiality. Participants will be recruited by a research panel provider and directed to an online Qualtrics survey to participate in the study. The research panel provider does not have access to participant responses, which are accessible only by members of the research team. The research team match responses using a code identifier, and the code identifier of those who complete the baseline are provided to the research panel provider to invite participants to complete the follow-up. The research team do not have access to the identities of participants.

Data deposition. Prior to publication of the results, data will be stored securely on Qualtrics and then the Griffith University Google Drive or OneDrive allocation and will be accessible only by authors K.H and J.J.K. Once data collection is complete, the data will be transferred to author M.S.H. Given the restrictions on access to the data, a data monitoring committee will not be required. Following publication, deidentified data and statistical code will be made available on Open Science Framework.

Dissemination. The findings are presented in the form of peer-reviewed journal articles and industry reports and presented at scientific conferences. The authors of this protocol will author publications arising from this trial. Media releases and public statements about the research are also made to disseminate the findings to the general public. The findings are also made available to participants if requested. Contact details and procedure for requesting the results are made available in the study information sheet. Trial materials are made available on Open Science Framework following publication of the results.

Discussion

The purpose of the current project is to evaluate the effectiveness of a theory-based intervention using implementation imagery to change drivers' intentions to drive into floodwaters. The intervention will be delivered online using a survey tool containing a series of infographic videos that present intervention messages. Participants will be randomised to an intervention condition or a control condition. The videos presented to participants assigned to

the intervention condition will comprise a series of educational messages about the risks of

driving into floodwater and an exercise using implementation imagery. The videos presented to

participants assigned to the control condition will comprise the education messages only. The

primary outcome variable will be intentions to drive into floodwater, and secondary outcomes

will be theory-based constructs identified as important determinants of intentions to drive into

floodwater in our previous research (provide references).

Driving into floodwaters is a high-risk behaviour that can be fatal. Reducing drownings

from risky aquatic activities during floods has been identified as a priority in the Australian

Water Safety Strategy 2016-2020 [12]. Strategies that change drivers' behaviour around

floodwater should be at the forefront of efforts to reduce drivers' propensity to drive into

floodwaters. The present intervention examines whether a behavioural intervention will be

effective in changing driver's intentions drive into floodwater. The intervention has been

developed with a focus on effectiveness and potential feasibility. In terms of effectiveness, the

intervention is based on psychological theories of attitudes, motivation and decision making,

consistent with research indicating that effective behaviour change necessitates a fundamental

understanding of behaviour, and that theory-based interventions can lead to more effective and

efficient interventions. The intervention content is based on formative research identifying the

determinants of risky behaviour when driving in floods and into floodwaters and is designed to

target change in behaviour through change in those determinants. In terms of feasibility, the

intervention has been designed to be delivered online and uses accessible infographic videos

co-designed by researchers and stakeholders. The exercises contained in the videos are

designed to be brief and cost-effective, reducing response burden, and maximising the

likelihood of engagement. If found to be effective, translation of the intervention into practice

will be facilitated by these design features. The brief, online design means it could be

incorporated in websites and disseminated through programs such as learner driver education

and during media campaigns during floods with minimal requirement for modification and at relatively low cost. It also paves the way for larger scale usability and feasibility trials.

The intervention will also make a contribution to theory. The current intervention adopts behaviour change strategies that target key theoretical determinants demonstrated to be related to risky driving behaviours around floodwater (reference our and others work). We expect our test of the intervention to contribute to the evidence base of effective methods for changing behaviour. Such evidence is important in order to identify the components of behaviour change interventions that are effective in promoting behaviour change and contributes to more effective and optimally efficient interventions.

A key strength of the study is that it uses a sample with key demographic characteristics proportional to the distribution of flood-related transport deaths in the Australian population, ensuring results are generalisable. While the outcomes are an extensive range of psychological variables established to predict driving into floodwater, the unpredictable and infrequent occurrence of flood events means that examining the effect of our intervention on actual behaviour is not feasible within the timeframe of the study. A limitation of the study is therefore that the primary outcome is behavioural intentions rather than behaviour. The paucity of high-quality theory-based intervention research is not unique to driving into floodwater. For example, for another behaviour that carries high risk of drowning, alcohol use during aquatic activities, there has not been any intervention research in more than two decades [39]. If effective, this type of intervention and mode of delivery may be developed and applied to other water safety behaviours with the potential to reduce drowning.

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Table 1

Behaviour change methods, targeted theoretical constructs, and implementation strategies.

Part	Behaviour change method/s	Implementation strategy	Target construct
1: Education	Information provision	Provide information about the risks of driving into floodwater	Attitudes, risk perception, perceived severity, perceived susceptibility
2: Formation of a goal intention	Personalise risk Scenario-based risk information Provide opportunities for social comparison Goal setting	Providing information about the personal risk; providing reasons people commonly drive into floodwater from prior studies; providing a strategy for overcoming barriers to avoiding driving into floodwater	Intention, attitudes, subjective norm, perceived behavioural control, risk perception, perceived severity, perceived susceptibility, anticipated regret, barrier self-efficacy
3: Practice imagery exercise	Guided practice (imagery skill)	Tangy lemon guided imagery task	Not applicable
4: Process mental simulation	Implementation intentions Goal setting Planning coping responses Guided practice Using imagery	Provide examples of things to do when floodwater is encountered; imagining the steps to use when encountering floodwater while driving; process mental simulation exercise	Intention, perceived behavioural control, barrier self-efficacy, action planning
5: Outcome mental simulation	Personalise risk Information about others' approval Provide contingent rewards Using imagery	Encouragement to think about the things that can happen when driving into floodwater and when avoiding driving into floodwater, including the risk and the benefits. Information about what important others will think; outcome mental simulation exercise	Intention, attitudes, subjective norm, perceived behavioural control, risk perception, perceived severity, perceived susceptibility, anticipated regret
6: Conclusion	Cue altering	Instructing that if ever in the situation to remember goal	Barrier self-efficacy

Note: Part 3 refers to the practice task which is designed to build imagery ability and does not relate to a target construct being assessed.

Running head: FLOODWATER DRIVING IMAGERY INTERVENTION PROTOCOL   25

Figure Legend

Figure 1. Randomised controlled trial design and participant progression through the study.

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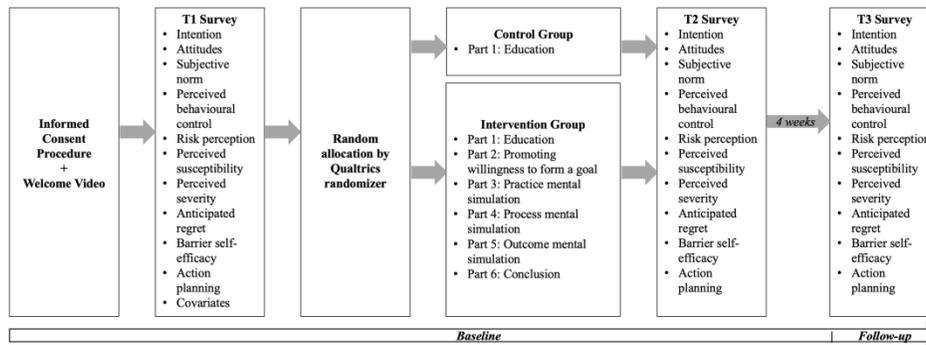49
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Figure 1. Randomised controlled trial design and participant progression through the study.

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Supplementary Material A – Mental Imagery Video Scripts

Note: The intervention group receives all of the below material. The control group receives the material indicated*. Italicised text is displayed on screen in addition to being read aloud.

*Welcome to the Study Video**

Audio	Video
Welcome to the study. Now that you have read through the study information and agreed to participate, I'd like to quickly recap what participating in the study today will involve. *First, there is a short survey for you to complete on the computer.* Then, *I will* be back to *guide you through some video exercises. Finally, I will leave you with another short survey to complete on the computer.* *Please now click to progress to the next page where the survey will begin.*	Neutral grey

Introduction to Activity Video

Intervention Group Audio	Control Group Audio*	Video
Thank you for answering those questions. For the next 10 or so minutes, I am going to guide you through a video.	Thank you for answering those questions. I am going to guide you through a video.	Neutral grey
In the video, I am going to provide you with some information about driving during flood events.	In the video, I am going to provide you with some information about driving during flood events.	
I am then going to guide you through some mental imagery exercises. In the exercises. In the exercises I will ask you to visualise several scenes in your mind.		
We will begin with a general imagery exercise to get you used to the idea and how it feels, and we will then turn to some exercises related to avoiding driving into floodwater.		
Before we start, I would like you to make yourself comfortable and to make sure you are free from distractions. When you are comfortable and ready to begin, please click to play the next video.	Before we start, I would like you to make yourself comfortable and to make sure you are free from distractions. When you are comfortable and ready to begin, please click to play the next video.	

2

Part 1: Education*

Audio	Video
Between 2002 and 2015, 89 drowning deaths occurred as a result of driving into floodwaters.	Neutral grey
Any flooded road can be deadly. Just a small amount of floodwater can wash your vehicle away.	
The second you decide to push through floodwater, you will give up control.	
The size of your vehicle doesn't matter, nor whether you've driven the road a hundred times before.	
No one can predict what lies underneath the surface. Even gently-moving floodwater can wash away the road surface beneath.	

Part 2: Promoting Willingness to Form a Goal

Audio	Video
Driving into floodwater can affect anyone, including you. So, I would now like you to consider the potential for this to affect you.	Scenes from flood events
People are often tempted to drive into floodwater…	
To get home	
To get to work	
Because the other road takes longer	
Because they've done it before	
Because their 4wd can handle it	
Because others are driving through	
Because they think they can assess the risk and manage it	
But, it is incredibly risky.	
Driving into floodwaters puts you and your passengers at risk and it could be fatal.	
So, what I'd like you to consider today, is forming a goal to avoid driving into floodwater if you encounter it on your route.	
By considering the risks and thinking of a plan, you can avoid driving into floodwater. The best way to get started is to set a goal to avoid driving into any floodwater. You should aim to avoid driving into any floodwater. The mental imagery exercise will help you to achieve your goal.	
On the next page, there is a question to answer. Once you have answered the question, please proceed to the next page and play the video.	

3

Part 3: Practice Imagery Exercise

Audio	Video
We will now begin a general exercise to get you used to the idea of mental imagery and how it feels. When doing mental imagery, people often find it useful to close their eyes. So now, let's begin. The first exercise is to prepare you for the mental imagery exercise ahead. The idea is for you to just relax and visualise the images as I talk you through it. So, imagine this scene. You are in your kitchen. In front of you there is a chopping board and a sharp knife. On the chopping board is a large, round, ripe, bright yellow lemon. Look closely at the lemon. *[5 second pause]* Pick up the lemon. Feel the lightly pitted texture of the peel, the vividness of the yellow of its colour, and the strong, tangy lemon smell. You rub the lemon gently with your fingers, and that causes the smell to grow stronger. The smell transfers to your fingers as you rub it. Hold it up to the light and look at it for a moment. Notice its colour and texture. *[5 second pause]* Now, put the lemon back on the chopping board. Pick up the knife and imagine yourself cutting the lemon down the middle. Feel the pressure of the knife handle on your hand as you cut into the lemon. See the juice burst out of the lemon, and cascade on to the board. Smell the intensity of the smell of the lemon juice. *[5 second pause]* Ok, pause there. You can open your eyes, but just stay relaxed. That completes the first exercise. The idea was to get you used to imagining a scene with great intensity and to familiarise you with how to use imagery. Often imagery is quite challenging for people. The idea is to actually feel as if you are there, 'in the moment', and to use all of your senses.	Lemon image

4

Part 4: Process Mental Simulation

Audio	Video
Now that you have practiced using mental imagery, I want you to use those skills in the following task, which will also require some imagery. The next exercise will help you to achieve your goal of avoiding driving into floodwater. Here are some examples of things you may do when you encounter floodwater: *- You could stop, and remind yourself that driving into floodwater is too risky. You could not worry about other cars that are waiting, or about how much you need to get to your destination.* *- You could pull to the side of the road and plan an alternative route.* *- And then you could turn around and follow your alternative route.* Now I would like you to go on to the next imagery exercise. [rain audio begins] Research has shown that you are more likely to actually carry out this intention if you 'mentally image' performing the intention in a very vivid manner, using your senses and imagination to make the imagery as realistic as possible. You will find that it might help to close your eyes when doing your imagery. If you wish, you can do so now.	Neutral grey
Now, please spend 2-3 minutes, imagining some steps you could use to avoid driving into floodwater. Think about a scenario where you are driving in your car immediately after a thunderstorm. You approach a section of the road that is completely covered in water. Think about all the things you would need to do in order to achieve your goal and think about all the things you would need to overcome.	Car at night in rain approaching floodwater
I will let you know when a few minutes have passed. [Visualisation exercise – 2-minute pause] [rain audio ends]	Black
Alright, now that you have finished your imagery, please note down in the space below a few sentences summarising the things you imagined you need to do to avoid driving into floodwater. It should be as detailed as possible. Writing down your images helps you to remember them more vividly. Spend about 2 to 3 minutes writing down your thoughts.	Neutral grey

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Part 5: Outcome Mental Simulation

Audio	Video
Please again make yourself comfortable and make sure that you are free from distractions. I am now going to guide you through some more imagery. Again, you may find it helpful to close your eyes. *[5 second pause]*	Car at night in rain approaching floodwater
Now think about the potential things that could happen if you drive into floodwater. *[10 second pause]*	Black
Now think about some of the outcomes if you avoid driving into floodwater. For example: It took a little bit longer, but you made it home safely. *[10 second pause]*	Car at night in rain approaching floodwater
	Black
Now, think about your goal to not drive into any floodwater. Now close your eyes again and imagine yourself having achieved that goal. *[10 second pause]* Think of all the effort you put in to achieving your goal now that you have finally accomplished it. Imagine the result of accomplishing this goal. *[10 second pause]* Think about all of the benefits you will gain: your safety and your passenger's safety; not suffering the expense of wrecking your car. Try to feel the satisfaction you would have with this accomplishment. Imagine a typical flood event and see yourself as someone who does not drive into floodwater. *[10 second pause]* Now, think about your loved ones, your family, children, and friends. What will they think if you achieved your goal to not drive into any floodwater? *[10 second pause]* Now you have finished your imagery, using the space below, please note down a few sentences summarising the positive benefits you imagined as a result of not driving into floodwater. It should be as detailed as possible. Spend about 2-3 minutes writing down your thoughts.	Car at night in rain approaching floodwater

6

Part 6: Conclusion

Audio	Video
Thank you for your attention, and if you're ever in the situation, please remember your goal. Please now proceed to the next page which contains some more questions for you to answer.	Neutral grey

7

Supplementary Material B

Items and response scales for measurement of psychological constructs

Behaviour	Definition
Driving through floodwater[a]	The following questions will ask about your knowledge and attitudes towards driving through floodwater. "Floodwater" refers to a body of water covering land that is normally dry. For the next questions, please think about your driving through floodwater. For example, think about the scenario where you are driving in your car immediately after a thunderstorm. You approach a section of the road that is completely covered in water. This could be any amount of water. Now consider your future driving, if such a scenario occurred, how likely are you in the future to drive through the floodwater…?".
Avoiding driving through floodwater[b]	The following questions will ask about your knowledge and attitudes towards driving through floodwater. "Floodwater" refers to a body of water covering land that is normally dry. For the next questions, please think about your driving through floodwater. For example, think about the scenario where you are driving in your car immediately after a thunderstorm. You approach a section of the road that is completely covered in water. This could be any amount of water. Now consider your future driving, if such a scenario occurred, how likely are you in the future to AVOID driving through the floodwater…?".

Construct	Items	Scoring
Intention[a]	I intend to drive through the floodwater. I expect I would drive through the floodwater. It is likely that I will drive through the floodwater. In general, I would be willing to drive through the floodwater.	[1] extremely unlikely − [7] extremely likely
Attitudes[a]	If I were to drive through the floodwater, it would be…	[1] bad − [7] good [1] harmful − [7] harmless [1] unwise − [7] wise [1] intelligent – [7] stupid [1] negative – [7] positive
Subjective Norm[a]	Most people who are important to me would approve of me driving through the floodwater. Those people who are important to me think that I should drive through the floodwater. Those people who are important to me would want me to drive through the floodwater.	[1] strongly disagree – [7] strongly agree

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	Those people who are similar to me would drive through the floodwater.	
	Most people like me would drive through the floodwater.	
Perceived Behavioural Control[a]	It is mostly up to me whether I drive through the floodwater.	[1] strongly disagree – [7] strongly agree
	I have complete control over whether I drive through the floodwater.	
	It would be easy for me to drive through the floodwater.	
	I am confident I could drive through the floodwater.	
Risk perception[a]	It would be risky for me to drive through the floodwater.	[1] strongly disagree – [7] strongly agree
	If I drive through the floodwater there would be risk involved.	
Perceived susceptibility[a]	My chances of having trouble if I drive through the floodwater are great.	[1] extremely unsusceptible – [7] extremely susceptible
	There is a good possibility that I will have trouble if I drive through the floodwater.	
	I would be worried about having trouble if I drove through the floodwater.	
Perceived severity[a]	If I drive through the floodwater, the consequences would be…?	[1] not at all severe – [7] extremely severe
	If you drive through the floodwater, to what extent would it impact severely on your life?	
Anticipated regret[a]	If I were to drive through the floodwater, I would feel regret.	[1] strongly disagree – [7] strongly agree
	If I were to drive through the floodwater, I would feel sorry for doing it.	
	I would feel upset if I drove through the floodwater.	
Barrier self-efficacy[b]	I am confident I can avoid driving through floodwaters in the future…?	[1] not at all confident – [7] definitely confident
	… even when I might be late for work	
	… even when I need to get to my children/other family members	
	… even when I need to get home to check on the house/pets etc	
	… even when the alternative route will take more time/is inconvenient	
	… even when I see others driving through	
	… even when I think I can make it	
	… even when I feel pressure from others to drive through	
	… even when I know others are around to help if something goes wrong	
	… even when I think my vehicle is capable to drive through	
Action planning[b]	Do you have a plan with regard to AVOIDING driving through floodwater next time you encounter it on your route?	[1] not at all true – [7] exactly true
	When to avoid driving through floodwater	
	Where to avoid driving through floodwater	
	How to avoid driving through floodwater	
	How often to avoid driving through floodwater	

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Imagery ability[c]	Typically, I…	[1] very inaccurate – [5] very accurate
	Have a rich vocabulary	
	Have difficulty understanding abstract ideas	
	Have a vivid imagination	
	Am not interested in abstract ideas	
	Have excellent ideas	
	Do not have a good imagination	
	Am quick to understand things	
	Use difficult words	
	Spend time reflecting on things	
	Am full of ideas	
Goal intention[c]	Now that you have heard some information about driving into floodwater, please indicate your agreement with the following statement:	[1] strongly disagree – [7] strongly agree
	I am willing to form a goal to avoid driving through floodwater	
Imagery fidelity[d]	Vividness: How VIVID was the mental image that you had of yourself avoiding driving through the floodwater?	[1] not at all vivid – [7] very vivid
	Clarity: How CLEAR was the mental image that you had of yourself avoiding driving through the floodwater?	[1] not at all clear – [7] very clear
	Detail: How DETAILED were the images that you had of yourself avoiding driving through the floodwater?	[1] not at all detailed – [7] very detailed
	Ease: How easy or difficult was it for you to create these images?	[1] extremely easy – [7] extremely difficult

Note: [c]covariate; [d]intervention group only

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Supplementary Material C – Informed Consent Materials

Investigating Driver Behaviour During Floods

INFORMATION SHEET

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Why is the research being conducted?
The aim of the current study is to develop an understanding of driver behaviour during floods. The research team requests your assistance in helping us with this research.

What you will be asked to do
Your participation in this project will involve completing a brief online survey that will ask questions about your knowledge and attitudes toward driving through floodwater. You will also be asked to provide some background demographic details. This information is not used to identify you in any way but rather it will tell us about the representation of the individuals participating in the study. In addition, you will be required to watch videos and then fill in another online survey. The study will take approximately 35 minutes to complete. One week and four weeks after completing these tasks we will contact you by email and ask you to complete another short questionnaire, which will take approximately 15 minutes. These videos will require sound and you will need to be in a place that is quiet and free from distractions. You may prefer to use headphones to reduce distractions from background noise. The survey has been optimised for computer delivery and may not work properly on smartphones.

Participant selection and/or screening
We welcome your participation if you have are an Australian resident with a registered driver's licence.

The expected benefits of the research
It is expected that this project will not directly benefit you. However, your involvement will provide valuable information about decisions regarding driving through floodwater and, therefore, may benefit others through a greater understanding of these processes.

Risks to you
It is unlikely that there are any risks greater than daily living involved with participation in this project. However, should you experience any discomfort due to undertaking this survey, Lifeline (13 11 14) offers a free 24 hour telephone counselling service.

Your participation is voluntary
Your participation in this project is completely voluntary and you may cease participation at any time. If you agree to participate, you can withdraw from participation at any time during the project without comment or penalty. However, once your responses have been submitted and we have de-identified them, you will be unable to withdraw. Your decision to participate will in no way impact upon your current or future relationship with Griffith University.

Your confidentiality

The information you provide will be treated confidentially and all comments and responses are anonymous. Please do not put your name on the questionnaire. Your responses to the questionnaire will form part of a large data response set, which will initially be stored by Qualtrics. Research data from Qualtrics will be downloaded and stored securely on Griffith University's Google Drive or OneDrive allocation. Data will be password-protected and accessible only to members of the research team. As required by Griffith University, all research data (survey responses and analysis) will be retained in a password-protected electronic file for a minimum period of five years before being destroyed. Participants will be given the opportunity separately to express consent to be contacted for the follow-up survey. These contact details will be deleted following conclusion of the follow-up survey. A personal code identifier will be used to match surveys. Participants' data will not be identifiable in any publication or reporting. In the interest of researcher transparency, a strictly de-identified version of the research data will be prepared and made available on the online open data repository Open Science Framework (https://osf.io/).

Consent to participate

Completion and submission of the survey will be accepted as informed consent to participate.

Questions / further information about the project

Please contact the research team members if you have any questions or require further information about the project.

Feedback to you

No automatic feedback will be given to you about the results of this study. However, if you participate and wish to receive a summary of the research results once the study has been completed, you can email the research team members.

The ethical conduct of project

Griffith University conducts research in accordance with the *National Statement on Ethical Conduct in Human Research*. If you do have any concerns or complaints about the ethical conduct of the project you may contact the Manager, Research Ethics on (07) 3735 4375 or research-ethics@griffith.edu.au. This project has received ethical approval from the Griffith University Human Research Ethics Committee (GU Ref no: 2017/895).

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	#3	Date and version identifier	N/A
Funding	#4	Sources and types of financial, material, and other support	22
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	22
Roles and responsibilities:	#5b	Name and contact information for the trial sponsor	22

sponsor contact information

Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	22
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-6
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	10
Objectives	#7	Specific objectives or hypotheses	5-6
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	7
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7-8
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-10

Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	N/A
Interventions: adherence	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	8
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10-13
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	13
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	7-8
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8
Allocation concealment	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed	8

mechanism		envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7-8
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	7-8
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	8
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	15-16
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14

Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	16
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	14
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	15
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	15
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	15
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	15
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	15
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	22
Data access	#29	Statement of who will have access to the final trial dataset,	15-16

		and disclosure of contractual agreements that limit such access for investigators	
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	15
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	16
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	16
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	16 & 22
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Supp C
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

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