The Essential guide to LifeGuide intervention development.

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1. Introduction

The Essential Guide to LifeGuide intervention development was written by the LifeGuide team at The University of Southampton, originally for use by internal staff and students. However, we feel it may be useful to share it with other people currently using and considering using LifeGuide. This document outlines the key things we have found helpful to think about when creating an online intervention. Trust us, thinking about them before you start developing your intervention may save you a lot of stress and time later on. We have a lot of experience using LifeGuide and we have come up with these tips to help you get the most out of LifeGuide and to help you avoid making common mistakes.

Before you begin, there are a couple of key things you should know about LifeGuide. The LifeGuide Community Website can be found at www.lifeguideonline.org. This website has a number of functions which are worth exploring, but mainly you will use it to store and share your intervention once you have developed it. Please note, you will not create and develop your intervention online. For this you will use the authoring tool.

The LifeGuide authoring tool can be downloaded from the LifeGuide Community website (https://www.lifeguideonline.org/releases/authoring). You should save this authoring tool to your hard drive. It can also be downloaded or copied onto a memory stick, but it is likely to be slower. You must not download the authoring tool onto a network drive or a shared drive as it will not function properly.

For use alongside the LifeGuide authoring tool is 'The Wiki', which can be found at https://wiki.lifeguideonline.org/wiki/Main_Page. The Wiki provides a step by step guide to the technical side of LifeGuide and logic writing. It also has a very useful logic dictionary. The Wiki will be referred to throughout this document.

It is worth reading the 'What is LifeGuide' section of the wiki before you continue with this document, found at https://wiki.lifeguideonline.org/wiki/1. What is LifeGuide.

The following paper gives an additional introduction to LifeGuide and can be found on the LifeGuide Community website:

Williams, S., Yardley, L., Weal, M. and Wills, G (2010) Introduction to LifeGuide: Open-source Software for Creating Online Interventions for Health Care, Health Promotion and Training. In proceedings Med-e-tel: Global Telemedicine and eHealth Updates: Knowledge Resources. Luxembourg, LU, 187-190.

2. Planning, designing and developing your intervention

Writing the content of an intervention

It is much easier to write and edit the content of an intervention using ordinary text files such as Microsoft Word. Using track changes in Word is very useful when several people are making comments, and adding and editing text. Some people also like to use PowerPoint to design what their web pages may look like before moving on to the authoring tool.

Having a non-web based final version of the intervention content is also extremely useful for documentation and for making any future modifications that may be required at a later date.

When writing the content of your intervention (in Word or PowerPoint), give each page a meaningful name and note this on the document. These names can then be used to name the pages within LifeGuide. If this is not possible, ask the person who is making the pages to note the LifeGuide page names on the corresponding pages within the Word/PowerPoint document. This will make it much faster to find pages if changes need to be made later on.

Planning the navigation of your intervention

Most commercial websites are flexible – they are designed so that people can click around a website, picking and choosing items they are interested in. Online behavioural interventions are often different. They often require a more 'tunnelled' approach which involves end-users needing to see certain parts of the intervention before going on to other parts (e.g. review last week's goals before learning new behaviours in the next session).

People who use online interventions are not always typical internet users and may therefore be fairly unfamiliar with the web. We suggest the following for clear navigation:

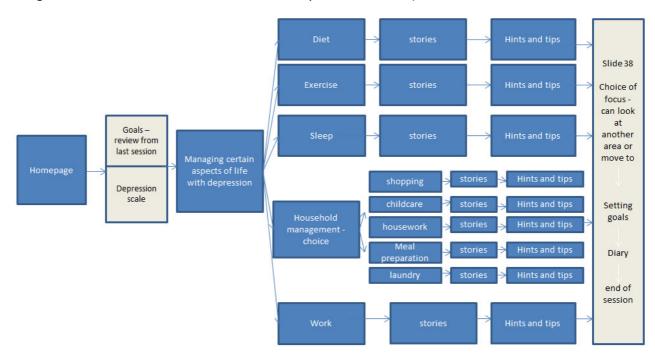
- Add Next buttons and Back buttons on pages (some end-users may not be aware of the Back button located in their internet browser). We find that having the Back button on the left and the Next button on the right (like an MP3 or DVD player), and placing the buttons in the same place on each page can be helpful to end-users. Remember that users may not be aware of the need to scroll up or down to find buttons.
- When adding links to external websites, put these links at the end of the session, otherwise you may lose end-users to other websites half-way through a session! Making these links appear as pop-ups will allow users to come back to your intervention easily.
- Pop-up windows or tabs may confuse some end-users and they may not know how to come back to your intervention. If you are using pop-ups to link to other pages in your intervention, you can minimise any confusion by putting a button on the pop-up page and adding the text Back to Main Website on the button (this is called a Close popup in the authoring tool). It can also be useful to provide instructions to your users that the link they are clicking on will open a new window or tab and that closing it will bring them back to the main website

Planning the navigation using flow charts

It is a good idea to create flow-charts before you begin creating your intervention, especially if you are creating a complex intervention. Flow charts are extremely helpful because:

- They will help you to see the bigger picture including how pages are linked and the different paths end-users can take when using your intervention.
- They can really help you with writing logic.
- They can help you to see where problems in the navigation or logic may occur before you've wasted a lot of unsuccessful development time.
- They are a key part of testing your intervention and ensure you test every possible use of your intervention. It is good practice for other people to test your intervention (see Section 4 of this document, 'Thinking about testing') and flow charts are a really good way of showing them how the intervention should work.

This is an example of a flowchart which shows how pages in an intervention connect (you may have a diagram like this one for each session/section in your intervention):



Creating your pages - using templates

Within the Authoring Tool you can create page templates. You can have several templates and each one may have the standard header, and the border, footer, back and next buttons in different places, depending on the length of the page. Some of your templates may not have back and next buttons, which will give you the flexibility of adding different buttons on the page itself. Creating templates will save you time, help your pages look more consistent and make your website look more professional.

It is important to finalise your template before you start creating pages. Making changes to the overall look once you have started is time consuming and should be avoided.

We suggest creating pages with a width of 1024 pixels. (See the wiki for how to change the default page width in the Intervention/logic file for all new pages that you create).

If you need some ideas for layouts, colour schemes, logos, etc., you can look at our demo interventions on the LifeGuide community website:

https://www.lifeguideonline.org/manager/intervention/listDemo

Creating your pages – the content

The demos will also give you an idea of how much information to put on a page and the type of language to use. A simple but key finding in our qualitative work on various online interventions is that **people won't and don't read long pages of text in an online intervention.** They generally don't read webpages word by word in the way they read a book. Instead, they scan the page, pick out individual words and sentences and look at images. It is best to keep the language simple and to a low reading age so that people with poor communication skills, poor reading skills and learning disabilities can understand the information.

We suggest the following:

- Use large font we find most people like font size 14 or larger, and this helps people with mild visual impairments.
- Simplify the language, use short sentences and be concise.
- Use clear font styles avoid unusual and complex styles.
- Cut text into smaller paragraphs (even using one sentence per paragraph if it helps). This can help the page feel less text heavy.
- Simplify the language, use short sentences and be concise. You can use this readability test tool http://www.read-able.com/ to measure the reading age of text, and to ensure you keep it as low as possible.
- You may also want to use the BDA dyslexia styling guide for accessibility found
 at http://www.bdadyslexia.org.uk/about-dyslexia/further-information/dyslexia-style-guide.html which contains a simple list of styling decisions that can be made to keep content accessible. The guide is written from the perspective of dyslexia accessibility but much of it is also good general styling advice.
- Use lots of empty space (e.g. between borders and text).
- Use bullet points to break text up people will be more drawn to reading a concise bullet pointed message than a wordy paragraph.
- Use bold to highlight the main points on the page even if users' don't read the whole page they can still get the main message from what is bolded on the page.
- Prioritise information put the main points at the top of the page.
- Put non-essential information (this is information that will not affect the use of the
 intervention or isn't key to the behavioural techniques being studies) as an optional clickthrough allowing interested users to pick and choose what they are interested in.

- Images can be used to break up text and reinforce meaning people love pretty pictures on a website. We are told this on a regular basis in our qualitative work.
- It is uncomfortable to have to read text going across the whole screen so keep the text width short. You could use boxes or lines to break the text into smaller columns.
- Try to fit what needs to be conveyed on a page so that end-users don't need to scroll down too much.
- Knowing who is behind the website adds credibility, so consider creating a **Meet the team** page, which has photos and information about the people who have worked on the project.

The screenshot below shows how the above advice was used to create a page for an intervention:



Important things to remember when creating pages

- When you create a new page, you will need to give it a unique name. The unique name is
 case-sensitive and we recommend using lower case letters for simplicity. This name will be
 used in the logic and will also appear at the top of the browser for end-users. For another
 name to appear to end-users, type it into the box labelled Page title in the authoring tool.
- Pages are listed in the authoring tool in alphabetical order so use a prefix for each page to
 make it easier to find and remember page names. For example, if you have several sessions
 in your intervention, prefix each page with the session number, then add a content related
 name, e.g. s1_goal_setting. Baseline questionnaire pages could start with b, followed by the
 page number and name of the questionnaire, e.g. b1_pets.

- Likewise, all images should have a meaningful name. Blind and partially sighted people may use screen reader software to identify and interpret what is on the screen. This software will use the name of the picture.
- Screen reader software will also read information from beginning to end. Therefore it is important that items are listed in the order you would like them to be read. Please see the wiki page on **Ordering items** for more information on this.
- The order in which you create your interactions on a page will be the order that they appear in the Excel spreadsheet when you download the data (more information about your data is provided in section 6). Be aware of this when you are moving interactions around on the page because it may be confusing later on if items are in a different order than you expected. Also, if your end-users' are filling in a questionnaire and using the **Tab** button to move to the next question, if your interactions are not in the correct order, the cursor will not move to the question they expect it to. Check to make sure that each question is next to the correct named interaction.
- When you add text to a page, it is very important to make sure the text box is bigger than
 the text inside the box. This is because some computer and internet browsers may
 automatically adjust the text to make it bigger. If the text box is not large enough, the text
 will move onto the next line and may overlap other text below it, which will make the text
 unreadable.
- Creating error messages will ensure end-users provide you with information that is crucial to you. The error messages you create will appear when users try to continue without entering a response to a question. See the wiki for more detailed information about error messages.

Using interactions

You will need your end-users to input information/answer questions throughout your intervention. The place where they input this information is called an 'interaction'. Interactions you can use include Single-choice, Multiple-choice and Numeric value (see the wiki for more information about interactions and which one you should use in each situation).

It is important to give your interactions short meaningful names because you will refer to them when writing the logic and they will become the variable names for your data analysis.

Important points to remember when naming interactions are:

- They need to be unique to a page.
- They are case sensitive. We recommend only using lowercase letters when naming interactions so that all of your logic can be written in lowercase letters and you don't need to remember when to use uppercase letters.
- We recommend using simple meaningful names so you know what they are referring to,
 e.g. age, gender, postcode.
- They must start with a letter, and after that can contain alphanumeric characters, hyphens and underscores only.
- They do **NOT** need to include the page name (when exporting the data you can choose to add the page name before or after the variable name).

Keeping track of your interactions using an interaction key log can be very useful for writing logic and data analysis. The interaction log will need to contain the following: page name, interaction name, the question being asked, the response options and the corresponding unique response names.

Tailoring

You can tailor the information end-users see. You can base this tailoring on a number of things including on their gender, age, randomisation group, or the information they have entered into an interaction. NB. You cannot tailor information based on what users have entered into a text-entry box, but you can re-show this information to users.

Randomisation

When deciding on the design of your study, you will need to decide how your end-users will be randomised. Please see the wiki for advice on randomisation logic.

If they are going to be randomised within the intervention, you will need to add an extra line of logic to ensure that if end-users click the back button, they cannot be randomised again. There is more information about this in the wiki, but below is an example of how this might look:

```
265
266 #GROUP ALLOCATION
267 show login_start
268 #Logic to ensure users aren't randomised twice
269 after login_start if (loadvalue(username, "group") = "leaflet") goto login_bookletgroup
270 after login_start if (loadvalue(username, "group") = "intervention") goto login_interventiongroup
271
```

You will also need to add extra logic to ensure that if people close their browser before they are randomised, they go back to the point before randomisation next time they log in, so they can be randomised. Please see the wiki for more detailed instructions.

Questionnaires

You can administer questionnaires within LifeGuide, but there are a few important things to consider:

- How many questionnaires are you going to ask your end-users to complete and over what time scale? (e.g. One at baseline, one after 6 weeks and one after 3 months)
- How long will you allow for end-users to complete each questionnaire? (e.g. 4 weeks per questionnaire)
- Will you send emails to remind users to complete questionnaires? If you do, you can cancel reminder emails once they have completed the relevant questionnaire.
- Ensure the questions are all relevant to your data analysis, as you do not want your users to lose interest due to long questionnaires. You may want to only make specific questions mandatory so that end-users can complete each questionnaire without answering every single question. See the wiki for details of how to put 'Error messages' on your pages.
- For some questionnaires, consider marking mandatory questions with an asterisk on the page so users know which questions they have to answer. You may not want to do this too

- often though as it may encourage users to only answer those with an asterisk and skip the other questions.
- Consider your data when creating questionnaire pages. If questionnaires are repeated, make sure you have separate pages for them. For example if the same questionnaires are repeated every month, duplicate the pages and show a new page each month this is vital for the way that LifeGuide exports data. It will also make it easier for you to write the logic for showing the questionnaires. Please see the wiki for more information on how LifeGuide data is exported.

Prioritising your intervention features

Since it is difficult to be sure how long development will take (it always takes longer than you expect!), it is useful to prioritise the functions you wish to include in your intervention. You can use the MoSCoW approach to identify functions you want:

- 'Must have' (essential)
- 'Should have' (important, but can be worked around if necessary)
- 'Could have' (nice to have but not critical)
- 'Would like' (for future projects).

Please see the project management session for more information on timing and prioritisation.

Credibility

Credibility is important as users often don't know who is behind a website and they may be unsure about whether they can trust the information. You can increase the credibility of your intervention by good writing - check for grammar and spelling mistakes, use high-quality graphics and include university/research council logos. A page which shows the members of your team and their area of expertise can also help to boost the credibility of your website.

3. Thinking about user accounts

Creating user accounts

If you have several sessions in your intervention, you will need to add pages where end-users can create a user account and log back in. Users often find this more difficult than you might expect!

We recommend that you make end-users use an email address as their username when they create an account because:

- End-users are less likely to forget their email address.
- This reduces the likelihood of end-users registering the same username multiple times.

On the home page you will need to direct new users and existing users to the correct pages of your website. Existing users need a 'Login' button and it needs to be obvious to new users how to register.

Sometimes end-users try to register multiple times when all they want to do is login, which causes real problems as it makes it impossible for the system to link them with their previous sessions and data. For this reason, we suggest a prominent 'Login' button and a less obvious 'Registration' or 'New user' link. Your home page may look something like this:



When creating user accounts, it is usual to save variables (using the **savevalue** logic command) and use them later in the intervention, e.g. a person's email address, study ID number and first name. If there are many variables that you want to save, we recommend using more than one page to record these variables as there can sometimes be problems with saving data when there are many lines of logic written after a page. Problems can occur when users click on the Next button several times

(due to the next page taking time to load), or when there are issues with users' internet connection. You can write extra logic to show an error page if data that you have specified hasn't been saved.

Once you have allowed users to create a user account, you can save data specific to the user. For example, if a user enters a goal in session 1, this can be saved and shown to them later in the session, or in a later session.

If you need to have more than one registration system, for example, one for participants and one for nurses, we recommend you do not put two 'Registration' or 'login' buttons on the same page. Even if you clearly explain that one is for the registration/login of nurses, and the other is for participants, there will be confusion. We recommend instead that you send the nurses a link to the first page of their registration, and leave the single 'New User' or 'Registration' button on the home page for participants. The link may look something like this:

https://www.lifeguideonline.org/player/play /power?thiz=login_confirmation&jumpto=nursehome where 'www.lifeguideonline.org ' is the URL of the website, 'power' is the name of the intervention, 'login_confirmation' is the name of the first page seen after users login, and 'nursehome' is the page you want to show first to users who click on this link. Simply replace these with ones relevant to your intervention.

Order of pages for new users

When new users first see the website, information should be presented to them in the following order:

- 1. Information about the study
- 2. Consent form
- 3. Questions on demographics
- 4. A page for them to create an account (email address, password, and study ID if applicable). You may want them to input some details twice (e.g. email address) to ensure they are correctly entered.
- 5. Baseline questions
- 6. Randomisation (if applicable)
- 7. Session 1 (if applicable)

End-users need to be given information about the study before they are asked to give informed consent. We ask for demographic information before they create an account so that if they decide that they do not want to create an account (some users don't like to give out their email address), we have some demographic information about end-users who chose not to take part in the study.

4. Thinking about emails

The role of emails in LifeGuide interventions

Emails are likely to play a large part in the running of your intervention. Emails are usually sent to end-users and the study team. Some of the most common emails sent to end users inform them of the following:

- Welcome to the study, your participant number is XXX.
- Your next session/questionnaire is ready for you to complete.
- Reminder your next session/questionnaire is waiting.

The study team will receive emails to inform them of end-user activity. For example:

- A new participant has registered.
- Participant XXX has not completed the 6-week questionnaire.
- Participant XXX has completed the study.

Please see the section on spamming to read about the legal issues you should consider when sending users emails.

Tips for creating emails sent by LifeGuide

Things to consider when writing emails:

- Use plain text. Colour, bold, italics and underlining cannot be used.
- Use paragraphs and spaces to separate information (\n\n and "" in the logic file)

The emails sent out by LifeGuide are automatically generated through the logic (see the wiki for more information about writing email logic). Some end-users may think these emails have been sent to them by a researcher. To minimise the number of end-users who reply to these emails, you can insert some text at the bottom of each email asking them not to reply to the automatic emails, e.g. 'This is an automatic email. Please DO NOT reply to this email as any reply will not be received. Please contact xxx@soton.ac.uk if you require assistance'.

If you are running a study, we recommend that you set up a new email account to receive study related emails for:

- end-users to contact you when they have questions or issues concerning the website.
- automated emails sent from LifeGuide regarding the end-users in a study, e.g. emails telling you that a new user has signed up or a user has not completed a questionnaire.

When writing the emails, it is important that you do not copy and paste from Word as some punctuation will not be recognised and will display as '?' in emails, and this can sometimes cause serious problems for the intervention email system. We recommend copying and pasting plain text from a program such as Notepad to avoid this issue.

Please also see section 7 of this document, 'Legal and security issues', which explains the legal issues you should consider when sending emails to users.

5. Thinking about testing

The testing process

An independent person must go through all questionnaires on the website and make sure that all the questions and response options are exactly the same as in the paper protocol. Check the website against the documents which have been approved by ethics to ensure everything is identical.

Testing is an extremely important part of development. It is a time-consuming and resource-intensive process, but well planned and detailed testing will ensure the smooth running of the website. This will help to increase website users' satisfaction and will also add credibility to the intervention.

Try to get lots of different users testing your intervention, not just your target audience. Recruit testers of different ages and abilities and people who know how your intervention works as well as those who don't. The more people who test your intervention, the more bugs/usability problems you will pick up before rather than during the trial.

When you are planning the project timescale, allow plenty of time for testing and the running of a pilot. We recommend that for interventions which have taken about 6 months to create, you allow a minimum of 2 months for testing and making changes. Be aware that once an intervention is live, any changes to the website cannot be made as this could result in losing data. It is therefore crucial to ensure that the intervention has been thoroughly tested before the final version is uploaded.

Before starting any testing, ideally before starting the development work, prepare a detailed flow diagram of the website. Although this may take a lot of time, it is priceless and saves more time at the end stages of development. It allows you to seeing the whole website layout and ensures all parts of the website will be covered during testing. A flow diagram is also an extremely helpful tool for communication between website developers and testers.

The first step of testing is writing a detailed testing script based on the website diagram. The script should include every single operation that needs to be completed by the tester. Below is an example:

Example of a testing script

All pages

Every link and button on every page should direct to the correct page.

Check for typos.

Check for formatting issues (overlapping text or boxes, text being cut off the page, etc.) in different web browsers (Internet Explorer, Firefox, Chrome, etc.).

Check print buttons print pages properly, i.e. that the pages are correctly formatted on the printout.

Check you can press the tab key and enter responses in the correct order.

Specific pages/functions

Consent page – check it only allows you to continue with the study if you have clicked 'yes' to questions 1, 2 and 4 on the consent form.

All links to external websites on the resources pages should work and should open in a new browser.

Check functions – registration, creating account, resetting password, logging in at various points in the intervention.

Goal setting (optional part which is near the end of sessions):

Session 2: you can set one goal

Sessions 3-5: you can set up to 3 goals

Check that if you have set goals in one session, they are shown in the next session.

If you haven't set goals in one session, you should not see the review goals section in the next session.

Randomisation

Check that if the study ID code is less than 500 (i.e. 000 – 499), participant should be in the leaflet group. If the study ID code is 500 or more, participants should be in the intervention group and can start session 1.

Questionnaires

Check questionnaires are available at the correct times:

- Baseline should be available immediately.
- 6 week questionnaires available 6-10 weeks from baseline. For testing purposes this will be 120 200 minutes.

If you close your browser whilst completing a questionnaire, you should be able to log back in and return to your previous position.

Emails

Check emails are received:

- When registration is complete
- When you've asked for a new password to be sent
- When each set of questionnaires are ready
- When each session is ready (intervention group only)

Ask testers to use the 'Play and Comment' mode on the LifeGuide Community website. They will need to create an account in order to use the website. 'Play and Comment' allows users to view the intervention as normal and make comments per page. You will be able to download an Excel spreadsheet with all of the comments and use a MoSCoW analysis to prioritise which comments to address.

Perform as much of the testing as possible on the server that you will be using when the website is live. It is good practice to test specific parts or functions of the website separately. Testing too many things at the same time may lead to omission of issues and makes the testing process chaotic. Ensure the login process, consent process and baseline questionnaires are also tested thoroughly as these will be crucial to the running of your intervention. It is a good idea to test these processes using 'think aloud' interviews.

Ideally, the intervention would be tested in real-time before going live. However, especially with long-term interventions, it is not always possible, so you can reduce the timescale. For example, you can reduce the timings so that one day = 10 min and 1 week = 70 min. These timings can be amended depending on which specific parts or functionalities are being tested.

Testing in different browsers

It is extremely important to test in different browsers as your intervention will look different and may function differently in various browsers. The most commonly used browser is Chrome, followed by Firefox, Internet Explorer and Safari. When new versions of browsers are released, they may have bugs that affect your intervention, so it is important to test different versions of browsers as well. A recent bug with Firefox (versions 29-34) affects how 'Back' buttons work with LifeGuide and we recommend inserting advice on this bug in the FAQs section of your intervention. Please see the section below on FAQs for more information.

We have uploaded some website support FAQ pages to help end-users who are experiencing problems with their browser. We recommend providing a link to the following page in your intervention to help end-users experiencing browser difficulties:

https://browserhelp.lifeguidewebsites.org/ We will update this page when necessary (i.e. when new browser bugs or other problems are found), which is useful as live interventions cannot be changed.

Testing emails

Emails can only be tested when your intervention has been uploaded to the LifeGuide community website or other server – emails will not be sent out in Preview mode.

LifeGuide logic cannot recognise formatted characters, so if you see a '?' in your email content, this is because a character in your email has special formatting (the most common reason is because the text was copied and pasted from Word). To correct this, simply replace this character with a plain text one in the logic file (you can use the Find and Replace function to correct them all in one go).

On the LifeGuide servers, emails are sent out at 5 minute intervals so bear this in mind when you are changing the timings to testing ones. If there are more than two types of emails, for example session reminders and monthly questionnaires, test them separately and together.

It is important to check that emails are being cancelled at the appropriate times, so make sure you give yourself enough time to complete questionnaires/sessions when you are testing that specific emails related to them are being cancelled.

When testing emails to the study coordinator, we recommend that you use a testing email address rather than the real one because when you go live, you may still receive testing emails and it may be difficult to distinguish between these and real study emails.

If you have more than one type of user account, for example, nurse accounts in addition to participant accounts, ensure the emails are tested for all groups of people.

The testing process

Every issue found during testing should be documented and reported to the development team, who should prioritise the issues. After an issue has been fixed, it needs to be re-tested. Be aware that changes to some parts of the website may affect other parts. Before the website is made available to users, the final version should be fully tested. Please see below for the order of the testing process and the testing checklist.

Testing process:

- Website diagram
- Testing while writing pages
- Writing testing script
- Testing specific elements (single pages, buttons, links etc.)
- Testing single sessions (if written separately)
- Testing integrated sessions
- Making changes
- Re-testing

Testing checklist:

- Appearance (e.g. overlapping text, location of page objects, etc.)
- typos
- tailoring
- interactions
- links (internal and external)
- buttons
- error messages
- email sending
- email cancellation
- deleting e-mails for participants
- registration process
- requesting and changing passwords
- data saving
- data organisation
- data download

- randomisation
- printing options
- page order
- sessions and between sessions questionnaires order
- formats of dates/phone numbers etc.
- test website in various internet browsers and different versions
- test for various operating systems

Prioritising problems

Testing may bring to light many issues to be improved. Problems need to be prioritised. For example, problems which affect the intervention use for study reasons (e.g. related to randomisation, baseline, follow-up data) will need to be given high priority. Whereas minor aesthetic changes will be much lower down the priority list. The MoSCoW analysis explained in Section 1 is useful for putting issues in order.

Running a pilot

The pilot of your intervention should be as real as possible and should be done when the intervention is complete. No major changes should be made after the pilot as these changes will need to be tested and could affect other parts of the intervention.

6. Thinking about your data

You will need to think about the data that is needed for your analysis before you start putting together your intervention. Clearly lay out the questions you need to ask your end-users, and the feedback you need them to provide, and plan this into the layout of your intervention.

Saving essential variables

Data entered as a response in an interaction (e.g. single-choice, multiple-choice, text-entry) will be automatically saved as **Session Data** in the Excel file. We recommend identifying essential variables related to your outcome measures and manually saving them in your logic file using the **savevalue** logic command (please see the wiki for details). This will ensure that your data is saved as **User Data** in the Excel file, so if there are any unexpected problems such as server issues or internet outages, your data will be saved (User data is saved as soon as users click on a button on a page, whereas **Session Data** is saved at the end of a session, so if there are unexpected issues midway through a session, **User data** will be saved, but **Session Data** may not).

Saving data

When developing your intervention, we strongly recommend identifying essential variables related to your outcome measures and saving them in your logic file using the **savevalue** function. This will ensure that your data is saved as **User Data** in the Excel file, and if there are any server problems or internet outages, your data will be saved (User data is saved as soon as users click on a button on a page, whereas **Session Data** is saved when a user finishes a session).

NB. In the Excel spreadsheet that you can download, responses entered into interactions are automatically saved in the **Session Details** sheet. Other variables can be manually saved using the **savevalue** command in the logic file and will appear in the **User Data** sheet. Please see the **How to Guide** on the wiki for further information on exporting data.

Check your data export before you go live

It is important to export your data before you go live to make sure that the data is in the format you want it to be. When you have uploaded your intervention onto the LifeGuide community website, you can export your data into Excel or a CSV file so you can see which variables are being saved and in what order. You can change the order the variables are saved (see the wiki for more information about ordering variables on a page).

Formatting cells in Excel

LifeGuide data is sometimes stored in a cell in Excel as **General** or **Text**. To use this data in a function in Excel or to import it into SPSS, you will need to change it to **Number** (in Excel 2010, right-click and select Format Cells, then **Number**).

Time split your data

LifeGuide allows you to look at how long each participant has spent on each page. However, if you have an intervention with many pages, it may be more appropriate to group pages together into meaningful sections and record the time participants spent on each section of your intervention. To do this, you will need to add sections to your logic. You can organise this in a way that best suits your analysis and the data you would like to obtain. Please see below for an example of sections you could group pages into:

- Registration
- Baseline questionnaire
- Follow-up questionnaire
- End of study questionnaire
- Session 1
- Session 2, etc.

Please see the wiki for information on the logic functions **begin** and **end**.

7. Thinking about legal and security issues

Spamming

Spamming is unsolicited email sent to a large number of addresses. It is illegal in many countries, including the UK.

It is good practice to send as few emails as possible to end-users so they do not feel as if you are spamming them. Generally, people do not like receiving a lot of emails and if they receive too many, they may not pay much attention to each one and may want to withdraw from the study. For more information, please see Murray, E., Khadjesari, Z., White, I., Kalaitzaki, E., Godfrey, C., McCambridge, J., Thompson, S., & Wallace, P. Methodological challenges in online trials. J Med Internet Res. 2009 Apr-Jun; 11(2): e9.

If you are sending emails to end-users, by law, you must let them know how they can stop receiving emails. You can do this easily by adding an extra sentence at the end of the email which says to contact the research team if they would like to withdraw from the study. You can then delete all emails to a particular end-user by using the 'Delete emails queued for a specific participant' button in the Intervention Manager.

You can give end-users the option of deleting specific emails themselves, e.g. reminder emails for questionnaires (see the wiki for more information about allowing participants to delete queued emails).

Privacy and Security issues

Some users may be concerned about the privacy and security of their data. To minimise the number of participants who fail to register because of these concerns, add a security page to the beginning of your intervention. This page should contain the following information/reassurances, along with any other security information relevant to your intervention:

- Your data will be available to the Research Team only.
- All data stored on computers will be password protected.
- Your data will be anonymised as far as possible using your Study ID.
- All paper study materials will be kept in a locked cabinet within a locked room.
- The University Firewall keeps the network as secure as possible.
- All our servers use HTTPS connection to improve security

EU Cookie Law

Cookies store or retrieve any information on a computer, tablet or smartphone. By law, users must be informed if cookies are used on websites they visit and give consent to their use (implied consent is allowed).

Below is an example of how people can be informed about cookies and how they are used in LifeGuide interventions. You must have a link to a cookie policy on a prominent page of your intervention.

"This website, along with most other major websites, uses cookies.

When you enter details into our website, a cookie is sent to your computer. A cookie is a small file that is saved on your computer which allows us to remember some information about you.

We use cookies to keep you logged in and to identify your current session. Our cookies do not contain any information that you enter into the website or information that would identify who you are.

To use our website you will need to accept our cookies on your internet browser. If you decide to block our cookies, the website will not work correctly and you will not be able to take part in this study."

8. Going live

Last minute checks

After testing and before uploading your intervention to the live server, please check the following in your logic file:

- Have you changed all testing times to real times?
- Have you changed the testing study coordinator email address to the real address (and tested the this to make sure that emails are being received)?
- Have you checked that your study URL is correct in the emails that you send to your participants? It should point to the live website address, which will depend on the short name that you give your intervention when you upload it to the live website.
- If you are using the online version of EQ-5D, have you changed the testing URL to the URL of the live version?

How to 'go live'

Before going live you will need to download the 'application for use of server' form, which can be found on the contact page of the LifeGuide community website: (https://www.lifeguideonline.org/contact/index)

Please email the completed form to the LifeGuide support team: <u>LifeGuideSupport@soton.ac.uk</u>

If the LifeGuide team approve your application, they will send you the link to the live server where you will need to create an account and upload your completed intervention. When creating an account, it is advisable to use your study name as the username (e.g. StressLess) instead of your own name, so the study team can log in using these account details.

If you are part of The University of Southampton please send a copy of your final intervention to the LifeGuide support team on the above address. The easiest way to do this is to send them an email with the link to the final intervention on the LifeGuide Community Server.

The Intervention Manager

The data in the Intervention Manager is confidential and can be seen and deleted by anyone who has the account username and password. Therefore, please only share the username and password with a select number of people directly related to the study.

Checking the data

We recommend downloading the data at least once a month to check that essential variables are being saved and everything is running smoothly.

9. Thinking about technical support

Contact for end-users

You will need to provide end-users with a contact email address and/or telephone number in case they need technical support. It is important to let users know if these lines of communication are not available 24 hours a day, 7 days a week.

Provide end-users with a 'Frequently Asked Questions' page

Think of the questions end-users may frequently ask and list the answers. This will cut down the amount of support you will have to provide. If you have lots of questions to list, group them by topic to make it easier for end-users to find what they are looking for. For a FAQ demo, please see **Demo Interventions** on the LifeGuide Community website. A screenshot of this demo is shown below where users are able to click on each heading to reveal the answers to each section:

Frequently Asked Questions

General RESTORE questions

- · What is RESTORE?
- · What will I get from RESTORE?

Technical questions

- · What is an Internet Browser and which one should I use?
- The website is really slow, is there anything I can do?
- I accidentally closed the internet without finishing the session
- MAC Users advice
- Tablets and Smart Phones
- Why is there a back button, can't I just use my browser button?
- There is a 'next' button but it is not working
- Why can't I access all of the sessions at the moment?
- Why can I only see the first one or two sessions?
- How do I use and save my fatigue diary?

Emails

- Why am I receiving emails?
- . I am not receiving emails
- I have got an email to say a new session is ready but I have not finished the session before, what should I do?

Non-technical user questions

- I have forgotten to use the website or check my emails for a while, does this matter?
- I don't understand what to do after sessions 1 and 2
- How much time do I have to do each session?
- Can I go through sessions I've already done again?
- Do I have to fill in the questionnaires and review my goals each week when I've done sessions 1 and 2?
- Do I have to click on every option in each session?

Back to Main Website

A recent Firefox bug (versions 29-34) affects how **Back** buttons work in LifeGuide interventions on PC's, tablets and phones (related to how data is cached). If a user has many browser tabs open and they click on a **Back** button, they may see the error **Document Expired**. In order to go back, users will need to click **Try again**, then **Resend**. Alternatively, users can download the most recent version of Firefox where the bug should be fixed. LifeGuide interventions weren't developed for tablets or phones, so we recommend that users use a PC to access interventions. We suggest that this advice is added to you FAQs page so users are aware of this issue.

Obtaining relevant information from end-users about their problems

You can produce a list of standard questions to ask end-users when they contact the study team with a problem. These questions can be used when trying to help users by email or by telephone. If, they have a technical question specific information may be helpful to you in solving the problem. Please see Appendix 1 for a list of useful questions to ask an end-user experiencing technical difficulties.

Standard email responses to user questions

It will save you time if you save some template emails to answer common questions. Although you may have tried to address as many issues as possible in your FAQ page, it is likely you will still receive some regular questions. For example, if a user emails you advising they are having trouble logging into the intervention, your standard reply could look like this:

Dear participant,

Thank you for your email. It is possible that a small error may have caused the problems logging in. I would recommend that you check the following:

- Have you clicked on the 'Login' button? (sometimes users' accidentally click on the 'register' button in error).
- -Have you entered the email address you used when you signed up to the study?
- -Are all capital and lowercase letters being entered correctly in the password?
- -Have you ensured there are no spaces entered into the email address or password?

Please do let us know if you are still unable to login and we can test the account and issue a new password.

Many thanks for your help with the study.

Best Wishes,

The Study Team

Deleting emails to participants

If participants no longer want to take part in the study and wish to cancel all study related emails, you can delete these emails for them. Simply login to the Intervention Manager and select your intervention. On the **Intervention Details** page, click on Delete emails queued for a specific participant, enter the participant's email address on the next page and click on **Delete Messages**.

10. Project Management

How long does it take to create pages and write logic?

Interventions always take longer to develop than you think! This is usually because it is difficult to know how long things will take and people tend to be over-optimistic.

The time it takes to develop your intervention depends on the complexity and quality you need to achieve. Assuming that the basic intervention materials have already been developed (e.g. in a Word document), here is a rough guide to the time it would take **one person** to **create** the pages and write the logic:

- a short twenty-item questionnaire with basic logic commands and no user account may only take a couple of days
- a detailed session for a CBT intervention with 20 pages linked by complex logic commands may take a month (double this for the first one you create, but by the time you are doing the last one in a series it may take less than 3 weeks)
- a 6 session intervention with full trial procedures (screening, questionnaires, randomisation, emails, etc.) may take 10 months.

Please note that the estimated times above do NOT include time for testing, making changes and piloting.

Important things to consider

If you are planning to run a trial, allow $\frac{1}{4}$ - $\frac{1}{3}$ of your development time for developing the trial procedures. Complex logic is required for trial procedures and it is important that you have enough time to write and test this logic.

Allow ¼ of your development time for testing, making changes and more testing! Testing is an important part of the development process.

Preview your intervention regularly so you know what your pages look like test your logic as you go along. Before you put the same piece of logic into every session of your intervention, make sure it is doing what you expect it to do. It is good practice to test that things are working the first time you add something new.

Planning your intervention

We recommend that you create a Gantt chart with project milestones. This will enable you to gain a better understanding of what needs to be done. Create milestones which are small enough to show progress with your intervention.

Work can often expand to fill the available time and some tasks can take longer than expected, but try to be realistic with your estimations of how long each part of your intervention will take to develop.

Your Gantt chart will be useful when communicating with your team. Your team will want to know if you are on track to completing your intervention or are running late. If you are running late, consider asking for an extra person to help if funding is available.

Changes to your intervention

During the development of your intervention pages, your team may ask for changes to be made to pages you have created. People may change their minds and/or their requirements, and some of these may add complexity to your intervention. A lack of agreement about what is important can lead to an increase in work that is beyond the original scope of the project.

It is important that you prioritise every suggested change with a MoSCoW analysis and that you communicate these with your team as making changes can impact greatly on your time. Projects can run behind schedule due to not fully understanding/knowing the impact of changes. Refer to the protocol if you are unsure of what is important. We recommend making deadlines for comments/changes to be suggested by your team so you are not continually changing existing pages.

11. Other important considerations

Managing expectations

Some end-users will have high expectations of interventions and compare it to established commercial websites. It may help to let your end-users know that it is a study website that they are testing and not a commercial website.

Likewise, the expectations of the wider study team (e.g. study co-ordinators) may be very high. It is a good idea to make the limitations of LifeGuide very clear from the outset.

Reporting an error with the website

If you are experiencing difficulties accessing the study website, please complete as many of the following questions as possible so that we can help you further.

	What is your Username (usually your email address)?		
2.	When did the problem occur?	Date:	Time:
3.	What web browser were you using? (Internet Explorer, Chrome, Firefox , Safari, etc.). What is the version number ? (e.g. 40.0.2214.111)		
Web browser :			
Version:			
4.	What device were you using to access the intervention? (PC, Mac, iPad, Tablet, Mobile, etc.)?		
5.	What were you trying to do when the problem occ	urred (log in, change your go	als, etc.)?
6.	What was the name of the page you were accessing when the problem occurred? This will be shown on the tab at the top of your browser window (you may have to hover over the name using your mouse to view the full page name). If you're not sure how to do this, you can copy the web address and paste it below (this doesn't show the actual page name, but will still be helpful to us).		
	using your mouse to view the full page name). If yo	ou're not sure how to do this,	you can copy the web
	using your mouse to view the full page name). If yo	ou're not sure how to do this,	you can copy the web
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