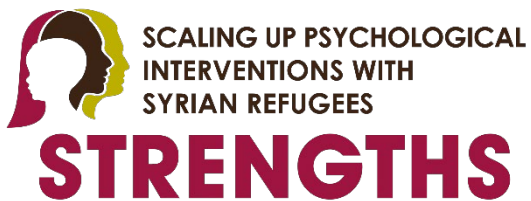




# WP6 / WP3

## Step-by-Step Hybrid App

Sebastian Burchert & Christine Knaevelsrud



## Aim of WP6

- **STRENGTHS Grant Agreement (WP6):**

*“The overall aim is to evaluate the dissemination of a generic electronic version (ePM+) as a scaling-up strategy in Germany, Sweden and Egypt (...)”*

- **“ePM+” is now “Step-by-Step”**

## Roadmap

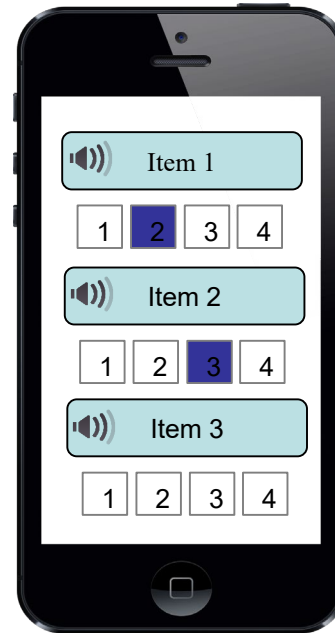
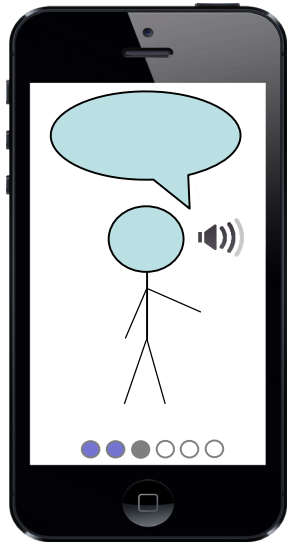
1. Live demonstration of the Step-by-Step Hybrid App and Admin Panel
2. Overview of 2018 and current status
3. Outline of contact-on-demand support
4. Conceptual framework of Step-by-Step software development
5. Next steps in WP6



## Live demonstration of the Step-by-Step Hybrid App

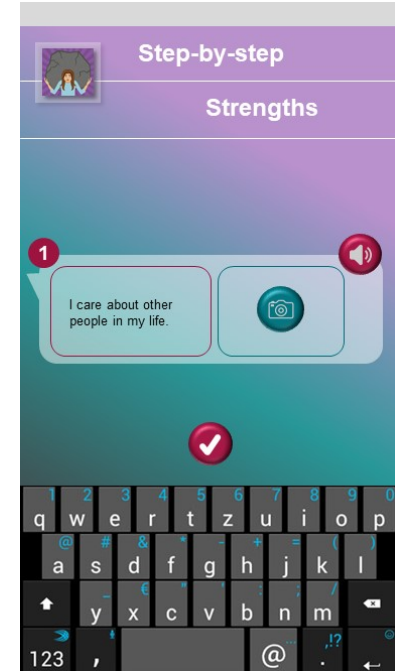
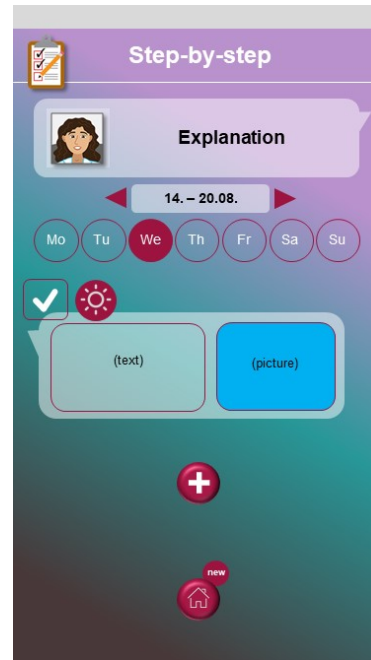
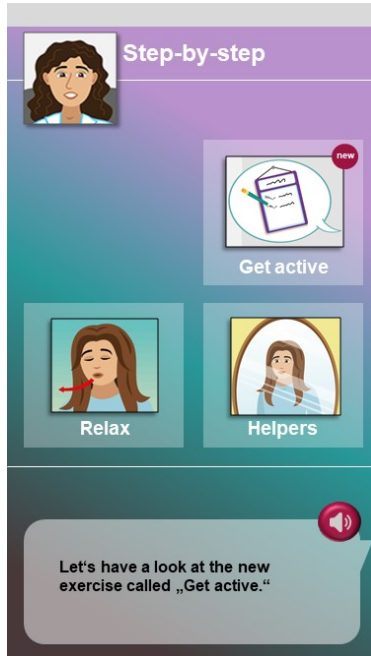
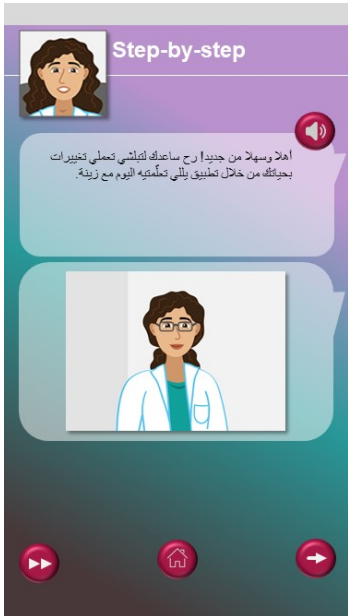
# The Step-by-Step Hybrid App

2017 early drafts



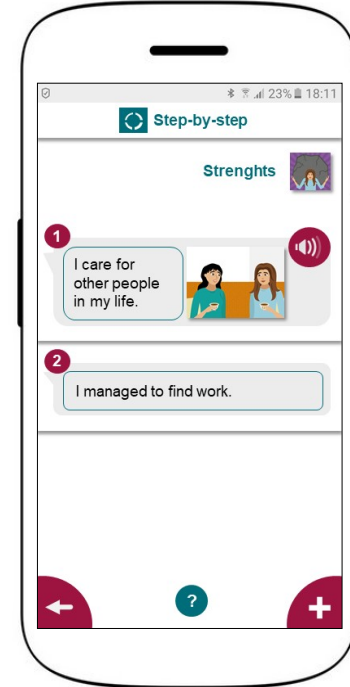
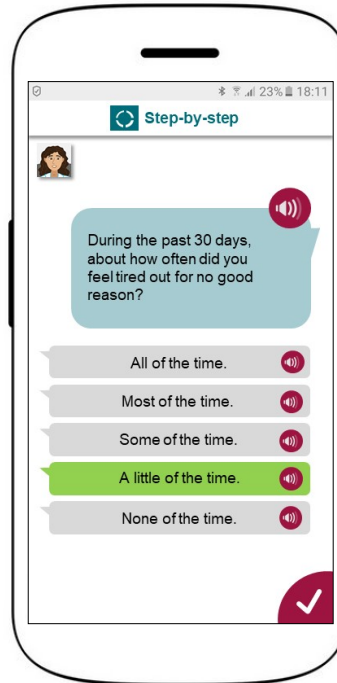
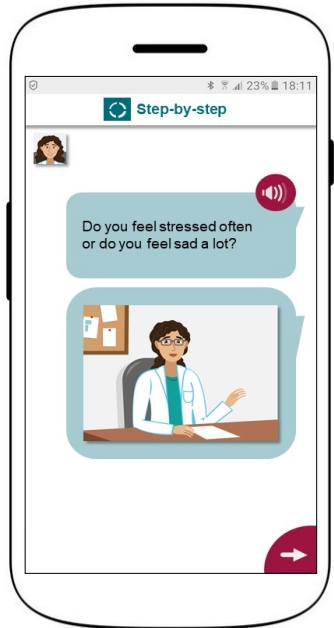
## The Step-by-Step Hybrid App

2017 mockups



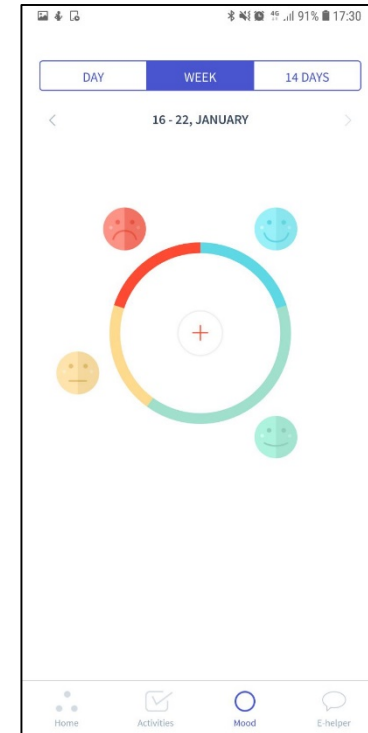
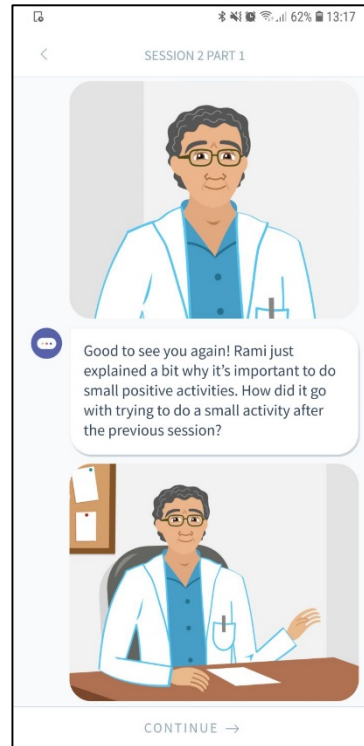
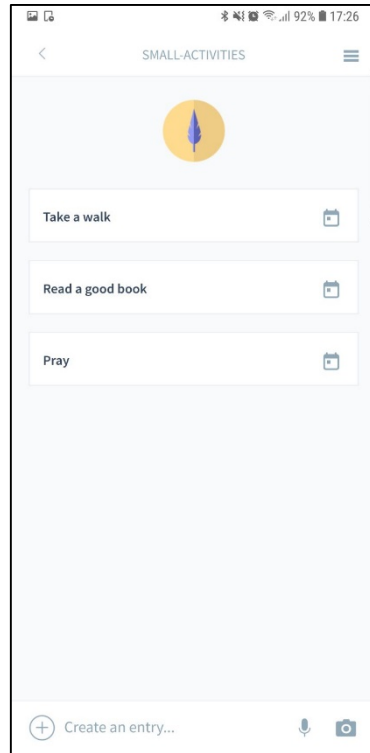
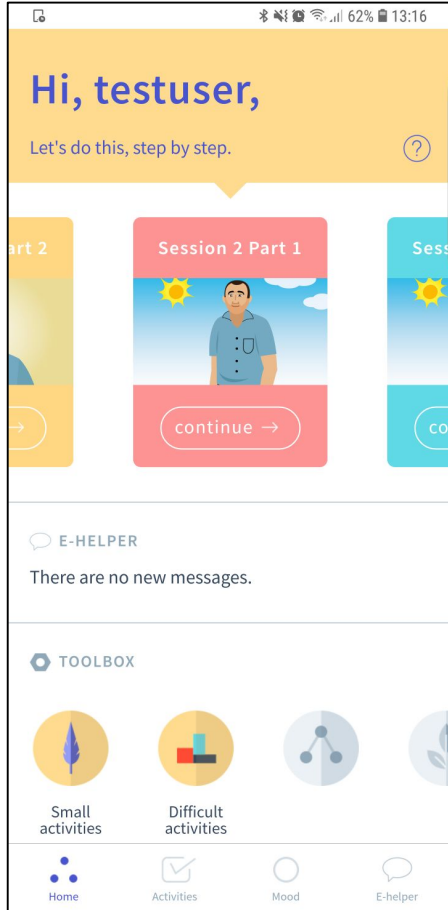
# The Step-by-Step Hybrid App

2018 mockups



## The Step-by-Step Hybrid App

2019 pilot version app







## Overview of 2018 and WP6 current status

## Main tasks

- Main task 1: **Adapt (WP3)**
- Main task 2: **Implement (WP6)**
- Main task 3: **Evaluate (WP6)**

## Main task 1: Adapt (WP3)

- T.3.2 Adaptation of Step-by-Step

*“The **pre-existing WHO concept** for electronic Step-by-Step will be further adapted and a culturally adapted **contact on demand** functionality will be developed.”*

## Main task 1: Adapt (WP3)

### ✓ T.3.2 Adaptation of Step-by-Step (2017)

- ✓ Sub-task 3.2.1: Desk research and consulting
- ✓ Sub-task 3.2.2: Qualitative assessment
- ✓ Sub-task 3.2.3: Adaptation of a generic electronic version and additional contact-on-demand
- ✓ Sub-task 3.2.4: Specification of technical requirements and data protection plan
- ✓ Sub-task 3.2.5: Detailed user-stories for all functions of the Step-by-Step platform

#### **First iteration(s) completed and reported on in:**

- Adaptation Report (D.3.1)
- month 18 technical report (still pending)
- Research article (Frontiers in Psychiatry)

**Iterative adaptation continued in 2018 and is ongoing...**

## Main task 1: Adapt (WP3)

- ✓ **T.3.3 Development of PM+ training material**
  - ✓ Sub-task 3.3.3: Step-by-Step training material for contact-on-demand
- **T.3.4 Pilot test and evaluation of PM+ training material**
  - ✓ Sub-task 3.4.1: Conduct pilot tests
  - Sub-task 3.4.2: Update training materials based on evaluation results
- ✓ **T.3.5 Conduct high-quality training-of-trainers in the PM+ manuals**

- **Report on training materials:**
  - Removed from D.3.2 but included in month 18 technical report
- **E-helper training materials are currently being finalized.**

## Main tasks

- Main task 1: **Adapt (WP3)**
- Main task 2: **Implement (WP6)**
- Main task 3: **Evaluate (WP6)**

## Main task 2: Implement (WP6)

- **T.6.1 Technical development and hosting of Step-by-Step**
- **T.6.2 Assessing approaches to integrate Step-by-Step into health care systems**
- **T.6.3 Preparation of implementation study protocol and ethical clearance**

## Main task 2: Implement (WP6)

- **T.6.1 Technical development and hosting of Step-by-Step**
  - ✓ **October 2017 - March 2018:** Procurement
  - ✓ **March 2018:** Software development started
  
  - ✓ **July 2018:** Completed first test version
  - ✓ **September 2018:** Revised and added content
  
  - ✓ **October/November 2018:** Internal testing and user testing
  - ✓ **December 2018:** Completed fully functioning pilot version



## Main task 2: Implement (WP6)

- **T.6.1 Technical development and hosting of Step-by-Step**
- **T.6.2 Assessing approaches to integrate Step-by-Step into health care systems**
- **T.6.3 Preparation of implementation study protocol and ethical clearance**

## Main task 2: Implement (WP6)

- **T.6.2 Assessing approaches to integrate Step-by-Step into health care systems**
  - Key informant and stakeholder interviews and informal discussions
  - 4 main approaches:
    - **outside of what health care systems cover**
      - filling gaps by being reaching those who would otherwise seek no help, e.g. through social media
    - **with local organizations/agencies (e.g. NGOs)**
      - e.g. organizations' client lists or waiting lists
    - **with local government agencies**
      - e.g. working with a ministry or regional authorities
    - **with international agencies**
      - e.g. WHO and UNHCR

## Main task 2: Implement (WP6)

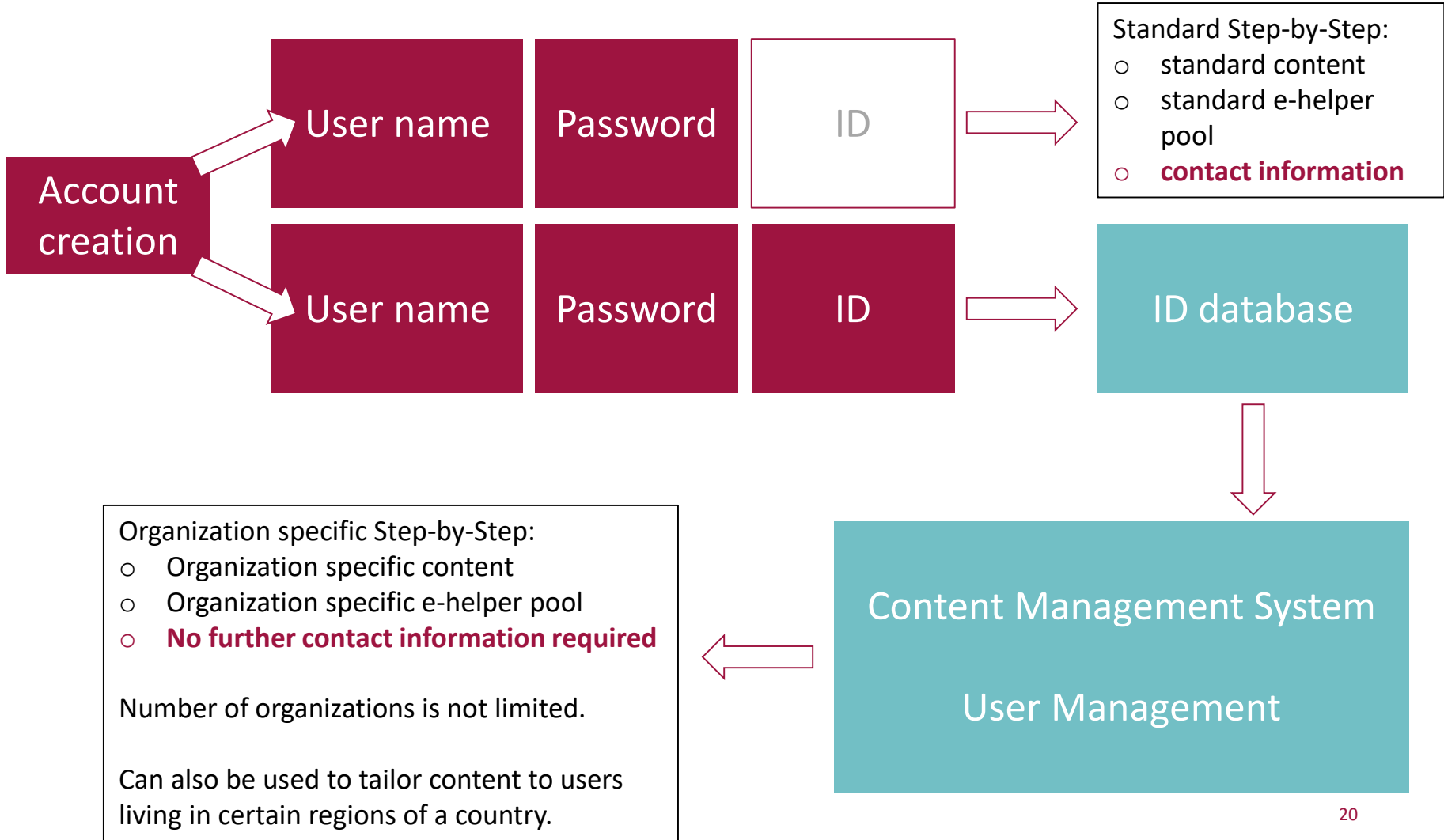
### ○ Example 1: UNHCR Egypt

- Potential local implementation partner in Egypt: Caritas in Alexandria
- Caritas has a UNHCR Egypt mandate to support refugees
- To officially work with Caritas, we need UNHCR Egypt approval
- One main concern: Privacy Protection

#### Measures taken as a result of stakeholder contact:

- Significant investment into privacy protection: **Organization ID System**
- Implementation of functionality that ensures 100% anonymous study participation for users who are associated with a local organization that UNHCR Egypt trusts.

# The Organization ID System



## Main task 2: Implement (WP6)

- **Example 2: Swedish Red Cross**
  - Plan to offer Step-by-Step to waiting list
  - Eventually SRC declined to offer Step-by-Step to its clients
  - Main reason:
    - Responsibilities as healthcare institution would extend to users of Step-by-Step, e.g.:
      - Taking action in case of symptom worsening
      - Referral to public health care system

### Measures taken as a result of stakeholder contact:

- Responsibilities cannot be removed but they can be made more manageable.
- **Access Token System:** Expansion of the Organization ID System. ID is used to provide a limited number of users access to an organization-specific version.

## Main task 2: Implement (WP6)

- **Example 3: WHO**
  - **Step-by-Step in Lebanon**
    - 2 studies: (1) Syrian refugees and (2) Lebanese general population → **feasibility RCTs began on January 9<sup>th</sup> 2019**
    - More than 100 participants within one week
  - Close cooperation between both teams
    - Content review; App testing; Additional user testing
  - WHO invested in rewriting the Step-by-Step story and created an additional story (for younger/unmarried users)

### Measures taken as a result of stakeholder contact:

- **Study Management System:** The platform can accommodate several studies at once. Each study can be customized (content, inclusion criteria, questionnaires, ...)
- **Revision of the narrative components:** New technical infrastructure for the new style of presenting the story. E.g. several protagonists in one narrative.

## Rewritten story: Example

### „old“ story

As well as feeling really sad, often I was angry too, arguing a lot with my family. I'd stopped seeing most of my friends. I didn't want to talk to people much anymore. I just couldn't enjoy anything.

In the end I told my friend Mona how I was feeling and asked her what I should do.

## Rewritten story: Example

**„new“ story by Helen Patuck and the WHO Step-by-Step Lebanon team**

I wasn't just sad. I was angry too.

I couldn't stop arguing with my family.

After a while I stopped seeing my friends. How could I explain this to them...

Besides, I was no fun to hang out with anymore...

I didn't want to talk to anyone.



## Rewritten story: Example

### „new“ story

Instead she came to my house.

She made me tea and gave me a long hug.

We sat together for a while. It could have been hours.

“I don’t know what to do, Mona,” I told her. “I have never felt so lost.”

## Main task 2: Implement (WP6)

- **T.6.1 Technical development and hosting of Step-by-Step**
- **T.6.2 Assessing approaches to integrate Step-by-Step into health care systems**
- **T.6.3 Preparation of implementation study protocol and ethical clearance**

## Main task 2: Implement (WP6)

- **T.6.3 Preparation of implementation study protocol and ethical clearance**
  - received ethical clearance in August 2017 (Ethics committee at FUB)
  - no additional local clearance for Sweden and Egypt yet
- **Reason for delay:** General Data Protection Regulation (GDPR)

## Main task 2: Implement (WP6)

- **General Data Protection Regulation (GDPR)**
  - in effect since May 25<sup>th</sup> 2018
  - June 2018: consultation of FUB IT department and data protection officer
  - Measures taken to comply with GDPR:
    - Revision of participant consent
    - Creation (and translation) of the Step-by-Step privacy policy
    - Creation of the Step-by-Step data protection documentation
      - Record of processing activities (Art. 30)
      - Data protection impact assessment (Art. 35)

## Record of processing activities (GDPR)

- **For each functional entity of the app** (e.g. configuration of the application) ...
  - **Purpose of data collection**
    - e.g. download of the gender specific version (text and audio files)
  - **Affected user groups**
    - e.g. study participants
  - **List of personal data**
    - e.g. gender
  - **List of receiving user groups**
    - e.g. e-helpers
  - **Deletion periods**
    - e.g. on completion of study, data will be anonymized, exported and deleted on the server

# Data protection impact assessment

- e.g. contact data

Damage category	Protection goal	Normal	High	Very high
Impairment of informational self-determination	Confidentiality			x
• e.g. damage to reputation	Integrity	x		
	Availability	x		

	Protection goal	Normal	High	Very high
Impairment of personal safety or health	Confidentiality			x
• e.g. risk of domestic violence	Integrity		x	
• e.g. symptom deterioration	Availability		x	

**Risk assessment and detailed description of risk mitigation measures.**

## Main tasks

- Main task 1: **Adapt (WP3)**
- Main task 2: **Implement (WP6)**
- Main task 3: **Evaluate (WP6)**

**The task has not started yet. Completed hybrid app required.**



## Outline of contact-on-demand support



## Contact-on-demand

### Main components of contact-on-demand

- E-helpers
- Chat feature of the app
- Admin panel for e-helpers
- Topic selection by users
- The Decision Tree
- Topic coding by e-helpers
- Answer template for e-helpers

## Contact-on-demand

### Main components of contact-on-demand

- **E-helpers** are ...
  - real humans
  - trained and supervised non-specialists
  - e.g. university graduates with a background in psychology
  - native Arabic speakers
  - in our case: Syrians (male and female)

## Contact-on-demand

### Main components of contact-on-demand

- **Chat feature of the app**
  - Chat is the main communication channel
  - integrated in the app
  - more secure than email
  - more compliant with GDPR than WhatsApp
  - more pragmatic/scalable than phone calls

## Contact-on-demand

### Main components of contact-on-demand

- **Admin panel for e-helpers**
  - List of clients (status, recent messages, ...)
  - Access to client cards
  - Access to chat
  - Case notes
  - Access to mood ratings and intermediate assessments

## Contact-on-demand

### Main components of contact-on-demand

- Topic selection by users

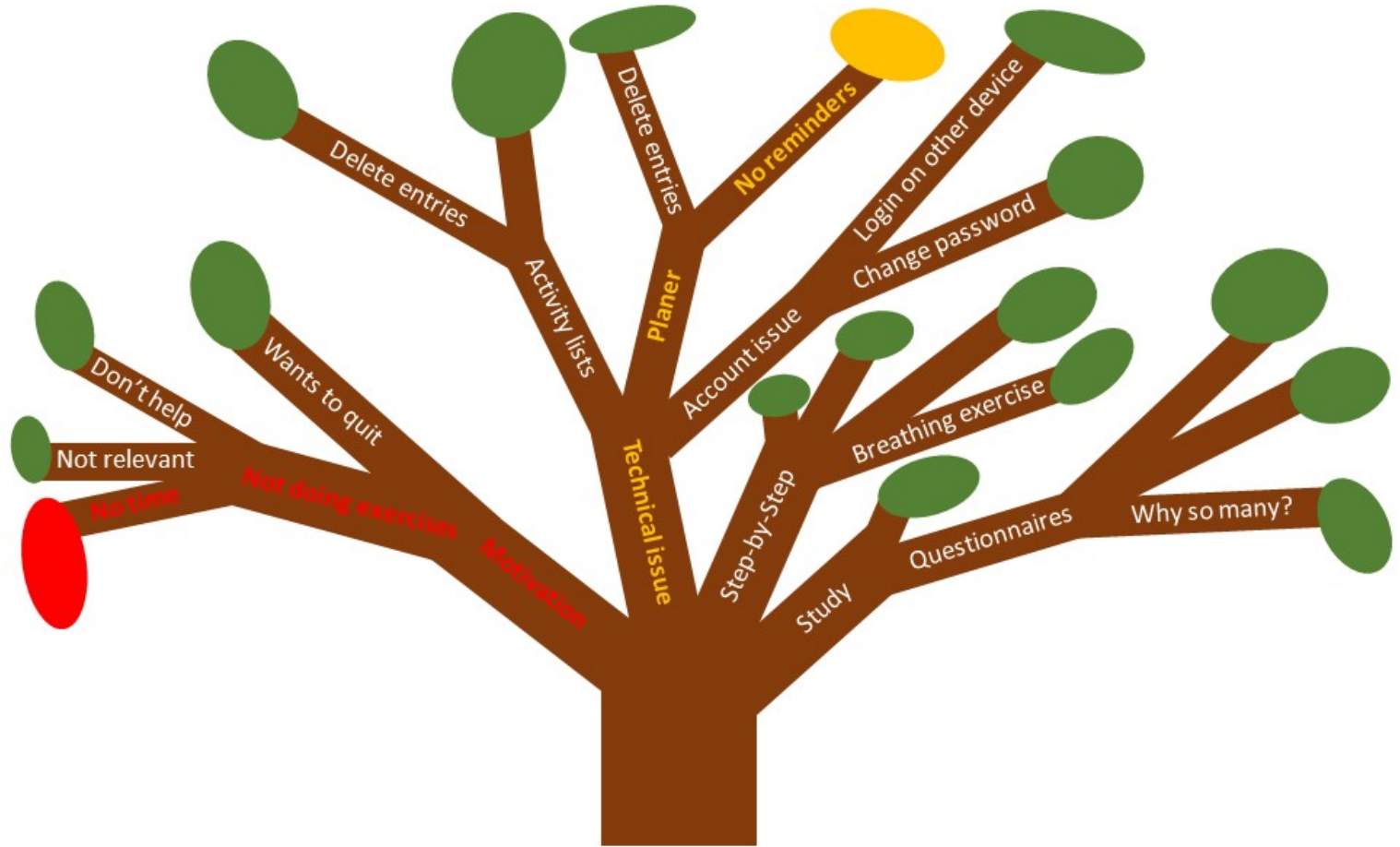
**Demonstration of chat and admin panel.**

# Contact-on-demand

## Main components of contact-on-demand

- **The Decision Tree**
  - system of potential contact-on-demand topics
  - will grow throughout the project
  - provides standardized answers to “known” topics in the form of text blocks
  - measure to ensure and observe fidelity

# The Decision Tree (early draft)



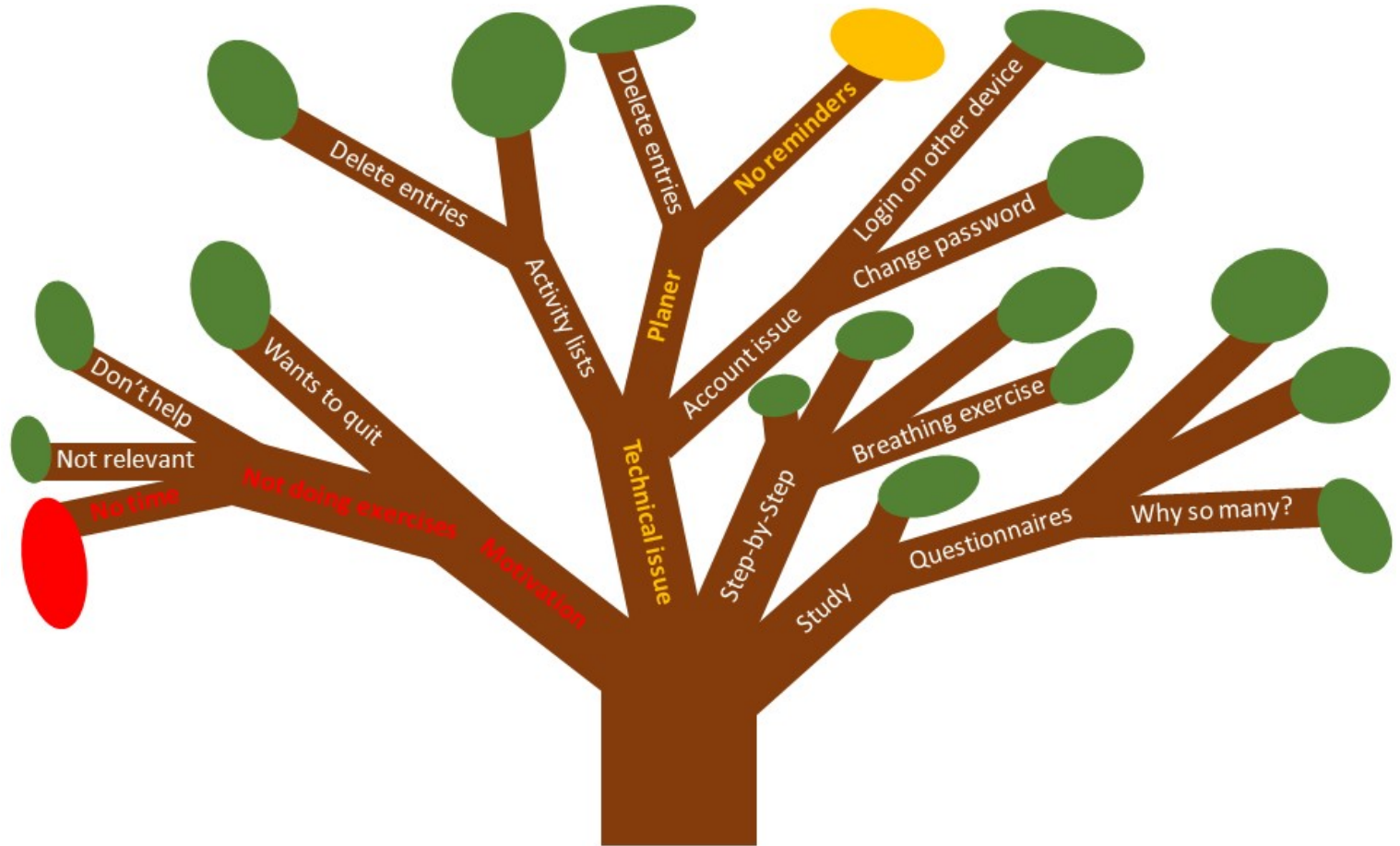
# Contact-on-demand

## Main components of contact-on-demand

- **Topic coding by e-helpers**
  - E-helpers identify topics within client messages that correspond to an existing arm of the decision tree



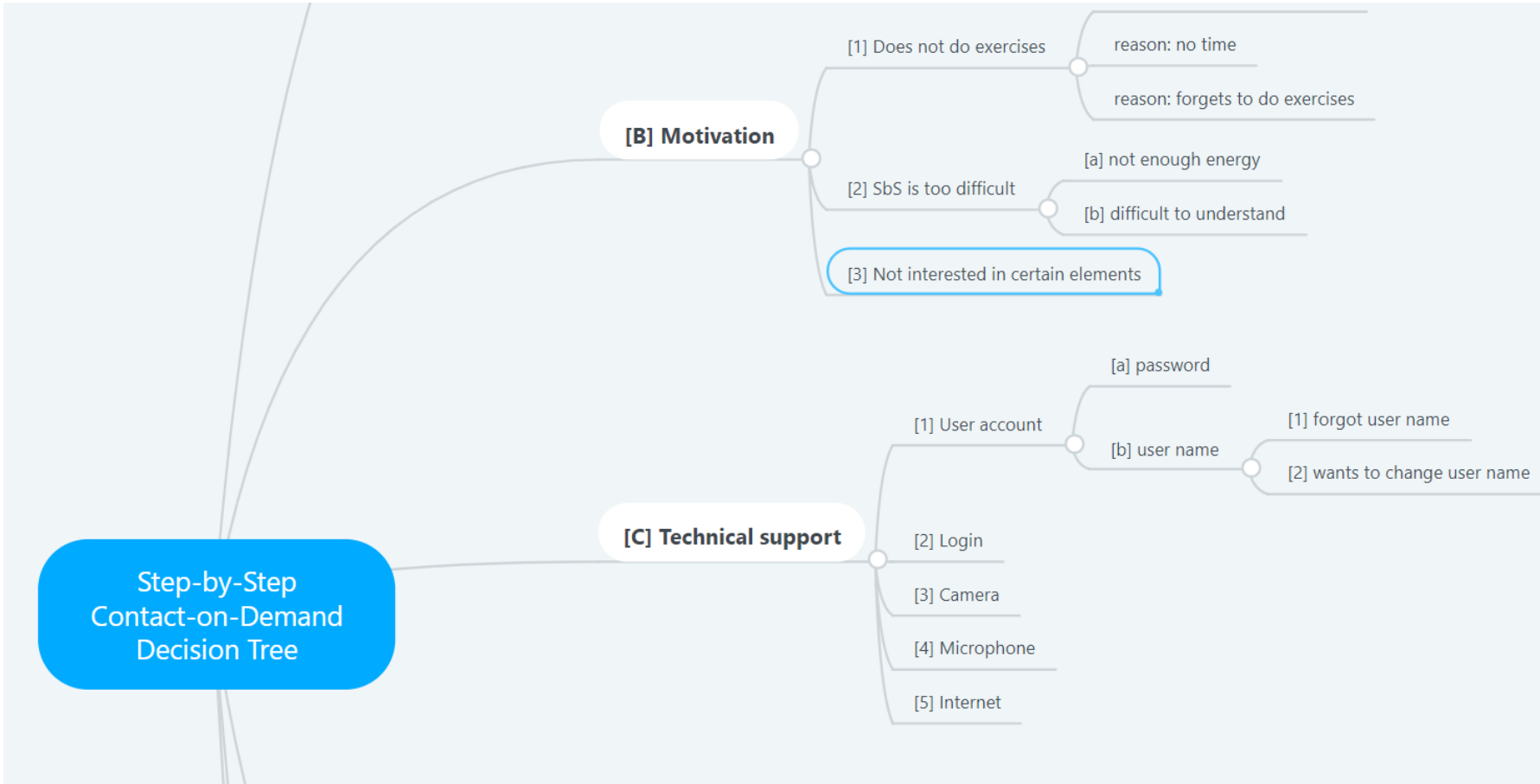
# The Decision Tree (early draft)



**User message:**

“Dear e-helper, I am using Step-by-Step and really like the story. But I realize that I have **no time to do the exercises**. I put some **in the calendar** but did not find time to do any of them. I also **did not get any reminders**, so I forgot some as well. Can I still continue using Step-by-Step?”

## The Decision Tree



# Contact-on-demand

## Main components of contact-on-demand

- **Topic coding by e-helpers**
  - E-helpers identify topics within client messages that correspond to an existing arm of the decision tree
  - e.g. “I don’t feel like doing Step-by-Step. I don’t have the energy to continue.”
    - **code: B2a**

## Contact-on-demand

### Main components of contact-on-demand

- Answer template for e-helpers
  - central element: text blocks
  - e.g. “I don’t feel like doing Step-by-Step. I don’t have the energy to continue.”
    - **code: B2a**
  - Text block for arm B2a:

Other users of Step-by-Step who might be in a similar situation to yours also reported that there is a lack of energy. Remember the ‘Sadness and withdrawal cycle’, and how it makes us feel less motivated to do things? Maybe if you start small, you will notice a small difference in your energy?

## Contact-on-demand

### Main components of contact-on-demand

- Answer template for e-helpers
  1. Greeting and introduction
  2. Rephrasing the topic(s) of the user message
  3. Use the text block(s) (phrasing can be modified, content not)
  4. Express appreciation for user's courage to contact you
  5. Say goodbye

Other users of Step-by-Step who might be in a similar situation to yours also reported that there is a lack of energy. Remember the 'Sadness and withdrawal cycle', and how it makes us feel less motivated to do things? Maybe if you start small, you will notice a small difference in your energy?

## Contact-on-demand

### Main components of contact-on-demand

- Answer template for e-helpers

Hello Testuser3. Thank you for getting in contact. My name is Sebastian.

If I understand correctly, you have difficulties continuing with Step-by-Step because you don't feel you have the energy to do so.

Other users of Step-by-Step, who might be in a similar situation to yours, also reported this lack of energy. Remember the 'Sadness and withdrawal cycle', and how it makes us feel less motivated to do things? Maybe if you start small, you will notice a small difference in your energy?

I can imagine that it is really difficult for you right now to start with something small that you enjoy doing and I want to say thank you for your trust in Step-by-Step and for contacting me about this.

I hope my answer helps you to keep going. If you have any questions or concerns, you can contact me again. All the best, Sebastian

# Contact-on-demand

## Main components of contact-on-demand

- Answer template for e-helpers
  - central element: text blocks
- If a topic is new: A new arm of the decision tree with one or several text blocks will be created by the study team
- The decision tree will grow throughout the project → **month 48 deliverable “contact-on-demand protocols”**

## Main tasks

- Main task 1: **Adapt (WP3)**
- Main task 2: **Implement (WP6)**
- Main task 3: **Evaluate (WP6)**

**Training of e-helpers**



## Main task 2: Implement (WP6)

- **T.6.4 Training of contact-on-demand providers**
  - First version of training materials were tested and refined with the help of two Syrian team members
  - Additional training will follow prior to starting the pilot trial
  - Training schedule:
    - **Part 1:** Self-guided use of Step-by-Step
    - **Part 2:** 4 face-to-face training days
    - **Part 3:**
      - 1 week of replying to 4 practice messages per day from home
      - 1 face-to-face training day to conclude training

## Main task 2: Implement (WP6)

- **T.6.4 Training of contact-on-demand providers**
  - **Part 3:** Replying to a series of practice messages from home and 1 face-to-face day to conclude training

### Examples of training messages:

- I did all of the exercises but nothing has changed.
- I would like to stop because it is too difficult and stressful.
- Could you please delete all my data?
- Why can I not start the next step right now?



# Conceptual framework of Step-by-Step software development

# Conceptual framework of Step-by-Step software development

STRENGTHS Hybrid App Platform

be widely  
accessible

separate of  
content  
and  
platform

be generic

support co-  
development

share / be  
open  
source

protect  
users

Create a scalable and reusable platform for  
contextually adapted e-mental health interventions

# Conceptual framework of Step-by-Step software development

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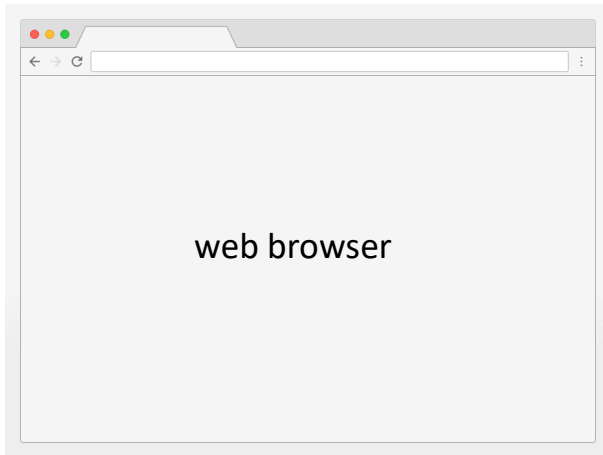
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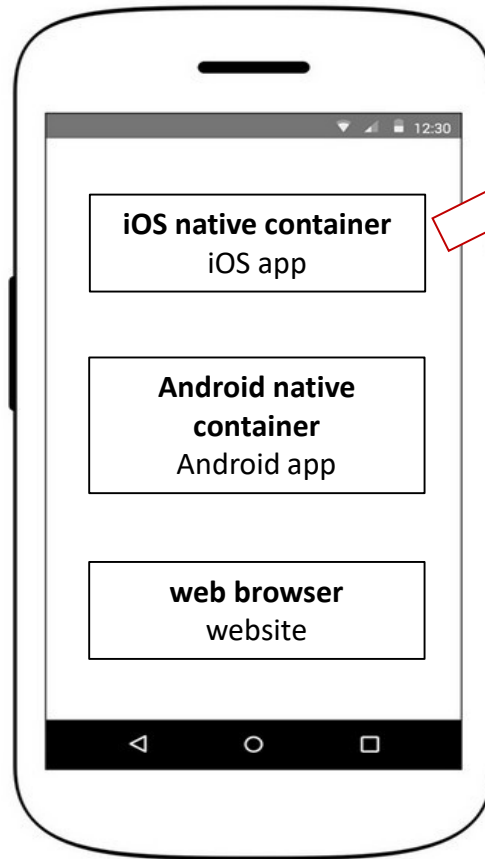
# What is a Hybrid App?

## website



**programming language**

- JavaScript
- (and HTML, CSS)



Plugins (camera, speaker, microphone)



## native app

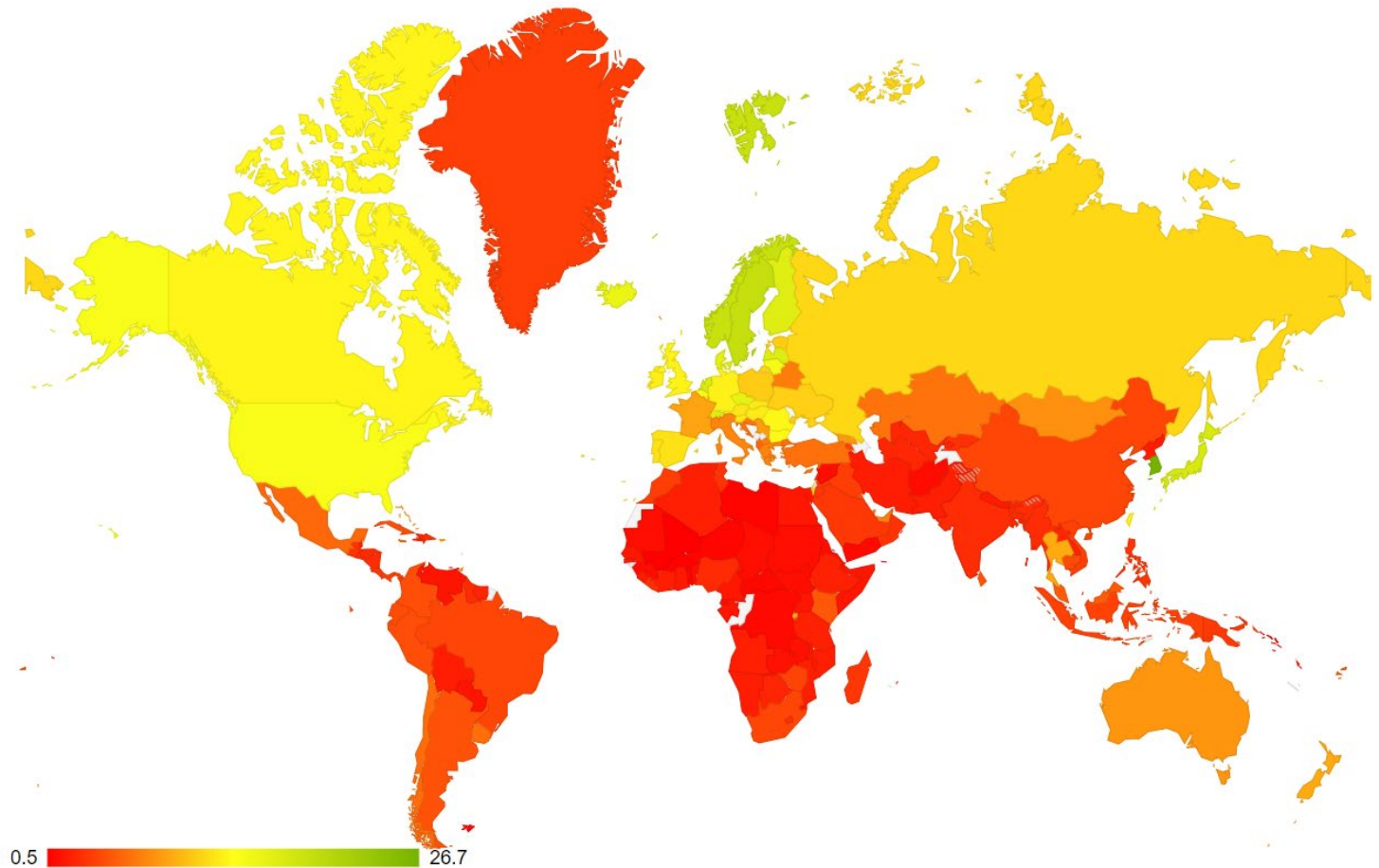


**programming language**

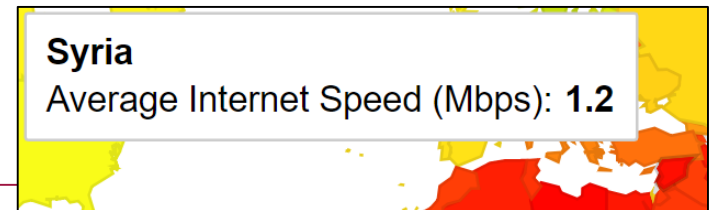
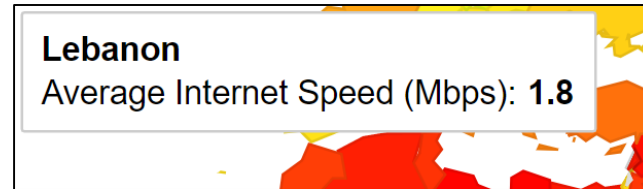
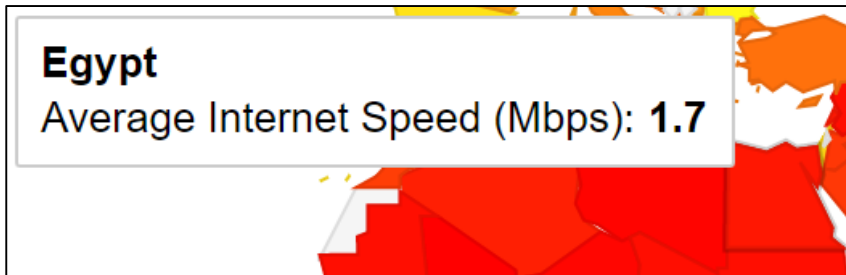
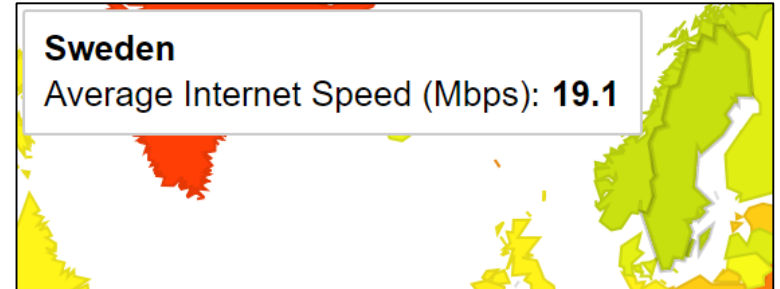
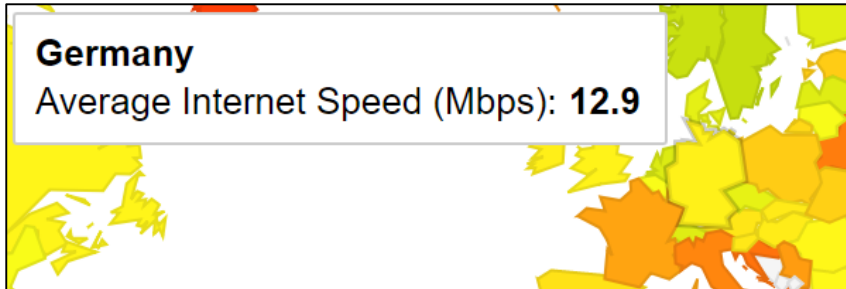
- iOS**
  - objective C, Swift
- Android**
  - Java, C++

## Biggest technical challenge

- Internet connectivity and speed



## Internet connectivity and speed



### 5 MB file download time:

- Germany → 3 seconds
- Sweden → 2 seconds
- Egypt → 24 seconds
- 4G → 0 seconds

+

unstable connectivity



# Conceptual framework of Step-by-Step software development

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share / be  
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protect  
users

Create a scalable and reusable platform for  
contextually adapted e-mental health interventions

# What is Step-by-Step?



[Mhealth](#). 2018; 4: 34. PMCID: PMC6131163  
Published online 2018 Aug 13. PMID: [30225240](#)  
doi: [10.21037/mhealth.2018.08.01](https://doi.org/10.21037/mhealth.2018.08.01)

Step-by-Step: a new WHO digital mental health intervention for depression

[Kenneth Carswell](#),<sup>1</sup> [Melissa Harper-Shehadeh](#),<sup>1</sup> [Sarah Watts](#),<sup>1</sup> [Edith van't Hof](#),<sup>1</sup>  
[Jinane Abi Ramia](#),<sup>2</sup> [Eva Heim](#),<sup>3</sup> [Andreas Wenger](#),<sup>4</sup> and [Mark van Ommeren](#)<sup>1</sup>

## Basic elements of Step-by-Step

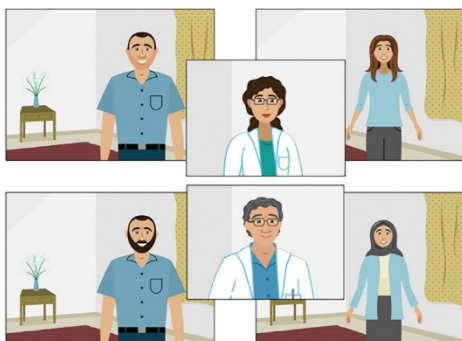
- Content
- Delivery system
- Guidance model

## Separation of content and platform



## Step-by-Step content developed by WHO

### Illustrations



### Narratives

Experiencing sadness and stress can lead to physical effects on our body. For some people, they may have headaches, muscle tension or feel sick in the stomach. It is also very common to feel very tired, as if you have no energy.

المرور بحالة حزن وضغط ممكن يسبب عوارض صحية. في ناس بييشعروا بوجع راس، وتشنج أكتاف أو وجع معدة. وكثير ناس بييشعروا بتعب شديد، وكان فقدوا كل حيويتهن.

### Therapeutic components / exercises

- Psychoeducation
- Relaxation: grounding and slow-breathing
- Behavioral activation
- Complex behavioral activation with difficulty management
- Increasing social support
- Relapse prevention
- Identifying personal strengths and positive self-talk

**Content can be adapted and expanded with permission from WHO.**

# Separation of content and platform



## Delivery system

- Step-by-Step content can be delivered via various delivery systems, such as:
  - Websites
  - Native apps
  - **Hybrid apps**
  - Books
  - Pamphlets
  - YouTube videos
  - Social media posts
  - ...

**The Step-by-Step content can be used to create interventions on the basis of a wide variety of dissemination media.**

# Separation of content and platform



## Guidance model

- WHO approach (Lebanon studies):
  - weekly e-helper contact (15-20 minutes) via phone or chat
- No guidance
  - fully self-guided use
- **STRENGTHS approach:**
  - Self-guided use with optional contact-on-demand

# Separation of content and platform



## Separation of content and delivery system

Step-by-Step content

+

STRENGTHS hybrid app platform

=

Step-by-Step hybrid app

The STRENGTHS hybrid app platform can be used to create different versions of Step-by-Step as well as hybrid apps based on other content.

# Conceptual framework of Step-by-Step software development

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users

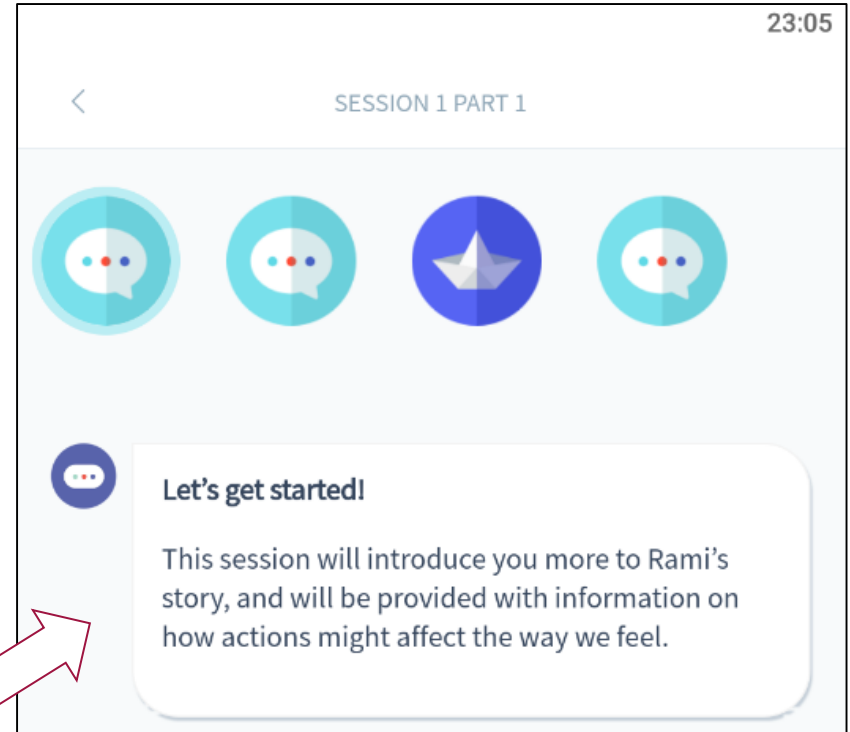
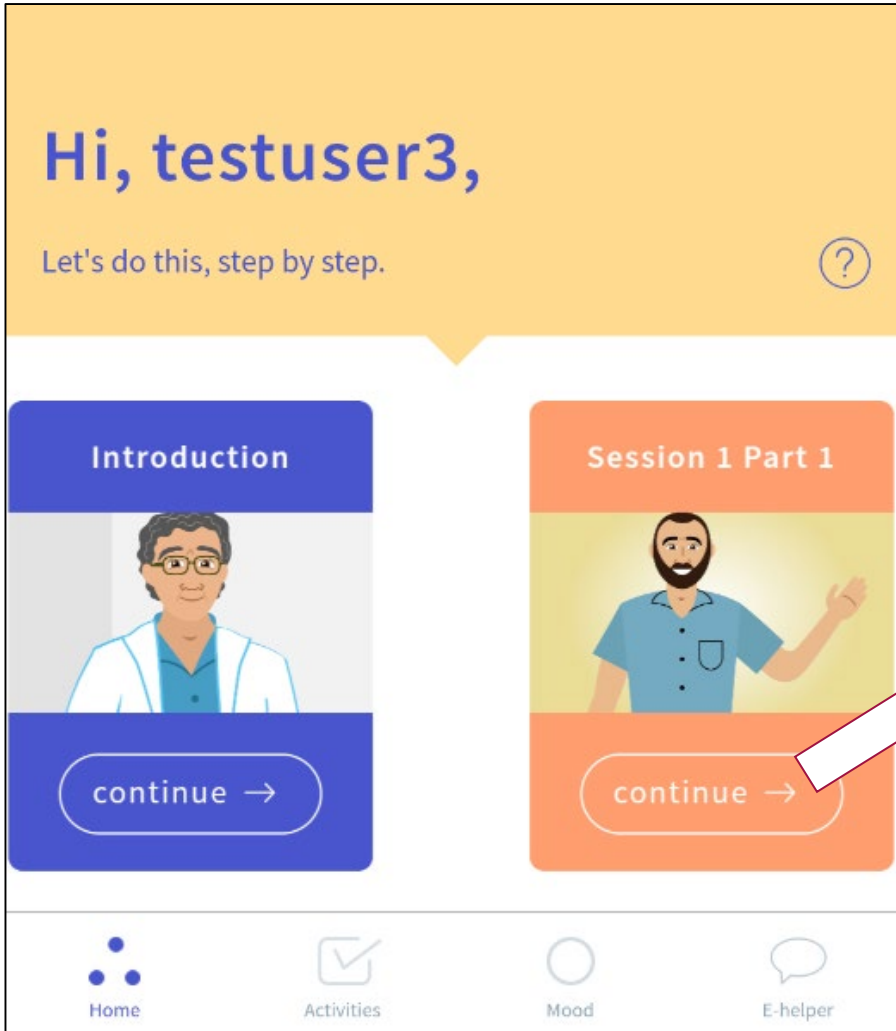
Create a scalable and reusable platform for  
contextually adapted e-mental health interventions

## Be generic

- **We hardcode as little as possible**
  - to maximise reusability
- Content templates
- Configuration logic
- universal elements
  - Calendar
  - Chat
  - Mood tracker



## Be generic



```
{
  "id": "sess1",
  "title": "SESSIONS.SESS1.TITLE",
  "image": "img_sess1",
  "wait": 24,
  "waitFrom": "last",
  "group": "treatment",
  "modules": [
    {
      "id": "narr6",
      "type": "NARR",
      "study": "all"
    },
    {
      "id": "narr7",
      "type": "NARR",
      "study": "all"
    },
    {
      "id": "grounding-exercise",
      "type": "ACTI",
      "study": "all"
    },
    {
      "id": "narr8",
      "type": "NARR",
      "study": "all"
    }
  ]
},
```

```
{
  "id": "sess1",
  "title": "SESSIONS.SESS1.TITLE",
  "image": "img_sess1",
  "wait": 24,
  "waitFrom": "last",
  "group": "treatment",
  "modules": [
    {
      "id": "narr6",
      "type": "NARR",
      "study": "all"
    },
    {
      "id": "narr7",
      "type": "NARR",
      "study": "all"
    },
    {
      "id": "grounding-exercise",
      "type": "ACTI",
      "study": "all"
    },
    {
      "id": "narr8",
      "type": "NARR",
      "study": "all"
    }
  ]
},
```

```
"narr6": {  
  "id": "narr6",  
  "blocksCount": 21,  
  "intro": "NARRATIVES.NARR6.INTRO",  
  "outro": "NARRATIVES.NARR6.OUTRO",  
  "blocks": [  
    {  
      "id": "1",  
      "image": "img_narr6_1",  
      "text": "NARRATIVES.NARR6.1",  
      "audio": "aud_narr6_1"  
    },  
    {  
      "id": "2",  
      "image": "img_narr6_2",  
      "text": "NARRATIVES.NARR6.2",  
      "audio": "aud_narr6_2"  
    },  
  ]  
}
```

## Be generic

- Translations are separate from content configuration
- Translation keys
- Translation files

```
"narr6": {  
  "id": "narr6",  
  "blocksCount": 21,  
  "intro": "NARRATIVES.NARR6.INTRO",  
  "outro": "NARRATIVES.NARR6.OUTRO",  
  "blocks": [  
    {  
      "id": "1",  
      "image": "img_narr6_1",  
      "text": "NARRATIVES.NARR6.1",  
      "audio": "aud_narr6_1"  
    },  
    {  
      "id": "2",  
      "image": "img_narr6_2",  
      "text": "NARRATIVES.NARR6.2",  
      "audio": "aud_narr6_2"  
    },  
  ]  
}
```

## Be generic

```
},  
"NARR6": {  
  "INTRO": "<b>Let's get started!</b><p>This session will introduce you more to Rami's story, and will be provided with information on how actions might affect the way we feel.</p>",  
  "OUTRO": "<b> Congratulations!</b><p>You will soon learn more about Rami.</p>",  
  "1":  
    "Hello my name is Rami. Dr Samer told you about me. Welcome to Step-by-Step! I did Step-by-Step some time ago with Dr Samer, in his clinic. In order to reach more people, it has been made into this programme.",  
  "2":  
    "We thought it might be helpful for you to hear about how the techniques in Step-by-Step helped me. I know my story will be different than yours, but I hope you still find it useful.",  
  "3":  
    "Step-by-Step may not be able to change everything in your life, but it can change the way you feel.",  
  "4":  
    "Every few days you will complete a new session and learn something new, just like I did with Dr. Samer. This session, we are going to learn about:<br><br>1. How stressful or negative events affect us,<br>2. How to start doing some small activities so that you begin to feel better.",  
}
```

# Conceptual framework of Step-by-Step software development

STRENGTHS Hybrid App Platform

be widely  
accessible

separate of  
content  
and  
platform

be generic

support co-  
development

share / be  
open  
source

protect  
users

Create a scalable and reusable platform for  
contextually adapted e-mental health interventions

## Support co-development

- **Psychologists can learn to code and can take an active part in software development**
- Text-based Content Management System
  - no graphical user interface (GUI)
- Every piece of content can be changed by the reserach team → (almost) no work by software developers required
- GIT → Version control system
- Make changes → push changes → automatic tests → merge



# Conceptual framework of Step-by-Step software development

STRENGTHS Hybrid App Platform

separation  
of content  
and  
platform

generic  
solutions

co-  
development

user  
centered

open  
source

secure

Create a scalable and reusable platform for  
contextually adapted e-mental health interventions

## Open source

- **We chose the European Union Public License**
  - EUPL 1.2
- Created and approved by the European Commission
- Available in all 23 official languages of the EU
- Code will be freely available and can be used for any purpose
- But: Any changes to the code have to be made available under the same license

# Conceptual framework of Step-by-Step software development

STRENGTHS Hybrid App Platform

separation  
of content  
and  
platform

generic  
solutions

co-  
development

user  
centered

open  
source

secure

Create a scalable and reusable platform for  
contextually adapted e-mental health interventions

## Secure

- Numerous data protection measures:
  - 2-factor authentication (for staff only)
  - Password complexity rules
  - Role permission system
    - Coordinator accounts
    - Case manager accounts
    - E-helper accounts
  - ISO 27001 certified web hosting provider
    - Firewall
    - Intrusion Detection System



**Next steps in WP6**

## Main tasks

- Main task 1: **Adapt (WP3)**
- Main task 2: **Implement (WP6)**
- Main task 3: **Evaluate (WP6)**

## Main task 2: Implement (WP6)

- **T.6.1 Technical development and hosting of Step-by-Step**
  - **January 2019 - April 2019:** Programming of definitive version
    - audio support
    - 2-factor authentication
    - revised narratives
    - UI changes
    - Admin panel convenience changes
    - Bug fixes
    - ...
  - **May 2019:** Testing the definitive version
  - **June/July 2019:** App is ready for pilot trials

## Main task 2: Implement (WP6)

- **T.6.3 Preparation of implementation study protocol and ethical clearance**
  - receive local clearance for Sweden and Egypt
  - receive WHO ethical clearance



## Main tasks

- Main task 1: **Adapt (WP3)**
- Main task 2: **Implement (WP6)**
- Main task 3: **Evaluate (WP6)**

## Main task 2: Implement (WP6)

- **T.6.5 Pragmatic trials**
  - Pilot in June/July 2019
  - Not in all countries at the same time
- **T.6.6 Outcome assessment in beneficiaries**

## Trials (overview)

- Pragmatic randomized (cost-)effectiveness trials with process evaluation
- Three separate trials with parallel design
  - Germany, Sweden and Egypt
- Two-armed design
  - A: Step-by-step app + enhanced TAU
  - B: Enhanced TAU

## Control condition

- (enhanced) treatment-as-usual (TAU)
- Enhancement:
  - Basic psychoeducation
  - Country specific list of facilities and contact information on where to receive care (can be organization specific if organization ID system is used)

## Trials (overview)

- 3 pilot trials with N = 60 participants each
- 3 definitive RCTs with N = 532 participants each
- Syrian refugees with elevated levels of psychological distress (K10) and reduced psychosocial functioning (WHODAS)
  - 18+ years
  - No plans to end their life (screening questions)

## Trials (overview)

- Expected effect size (primary outcome at 3-months):
  - Mean difference between both arms
  - $d = 0.4$
- Sample size calculation:
  - Power = .90 and alpha = .05
    - $2 \times 133 = 266$
  - Attrition of 50% at 3 months
    - $266/0.5 = 532$

### Overview of Measures (RCTs)

	Measures			
Concept	Screening	Baseline	Weekly	Post & Follow-up
Functioning	WHODAS 2.0			WHODAS 2.0
Distress	K10		K10	
		HSCL-25		HSCL-25
PTSD		PCL-5		PCL-5
Self-identified problems		PSYCHLOPS		PSYCHLOPS
Traumatic events		Trauma list		Trauma list
Post-migration stressors		PMLD		PMLD
Cost of care		CSRI		CSRI
Mood			Smiley-Scale	
Suicidality risk assessment	Screening item			
Demographics	WHODAS 2.0			
Access to health services		Access to care		
Usage data				Usage statistics
User satisfaction				Satisfaction questionnaire (post only)



**Thank you!**