

# **Translational Mental Health Research in the Family Context: Opportunities and Challenges in the Digital Age**

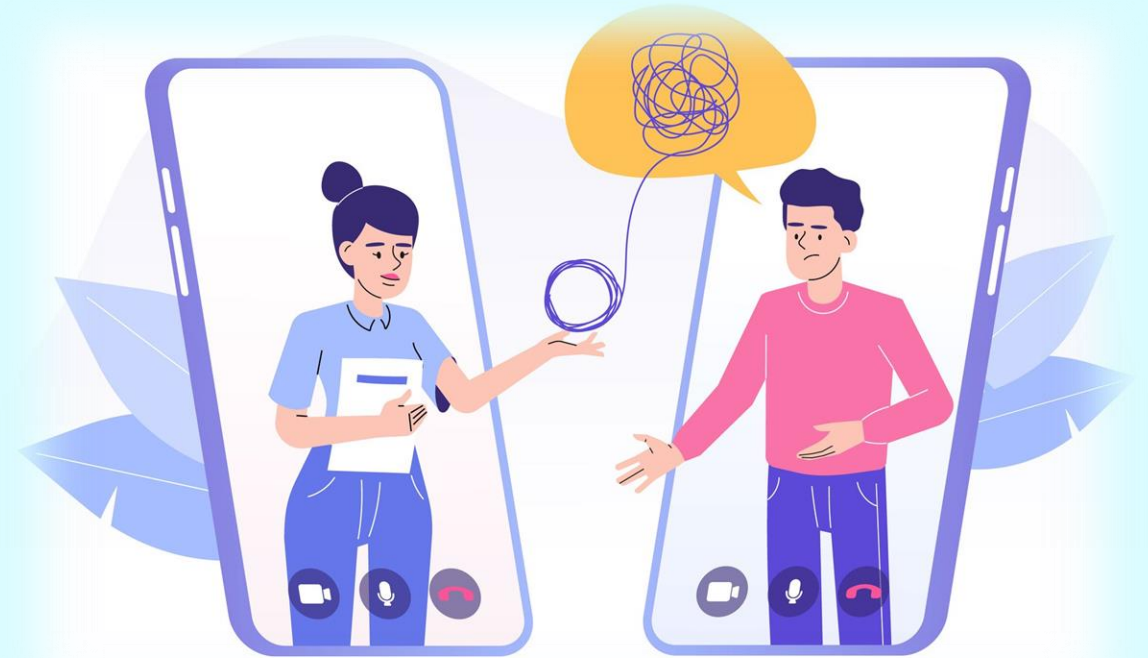
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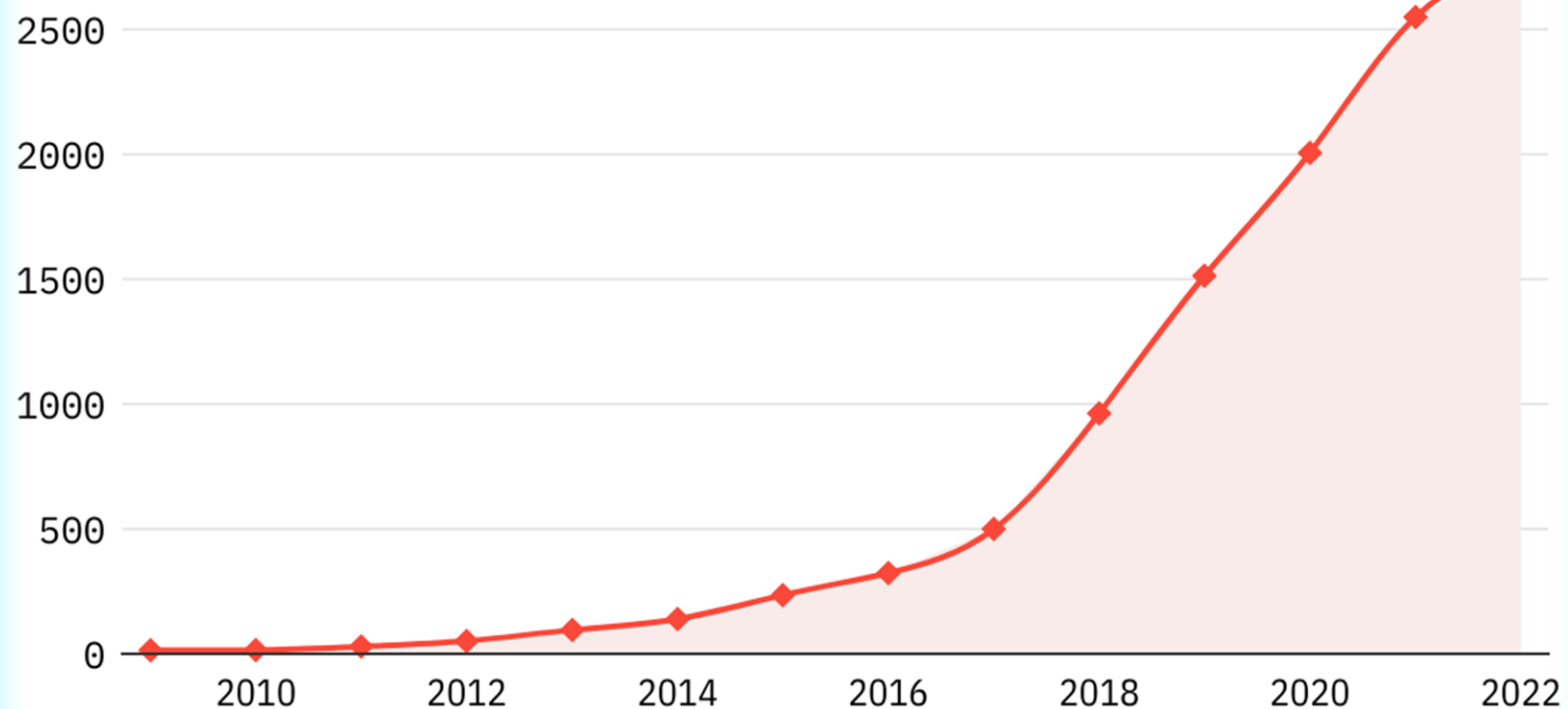
# Overview

- The Promise of Digital Mental Health
- Case Study: STOP (Successful Treatment of Paranoia)
- Opportunities in the Digital Age
- Challenges
- Pathways Forward



# Growth of mental health apps on iOS & Android stores

Cumulative volume of apps, 2009–2022



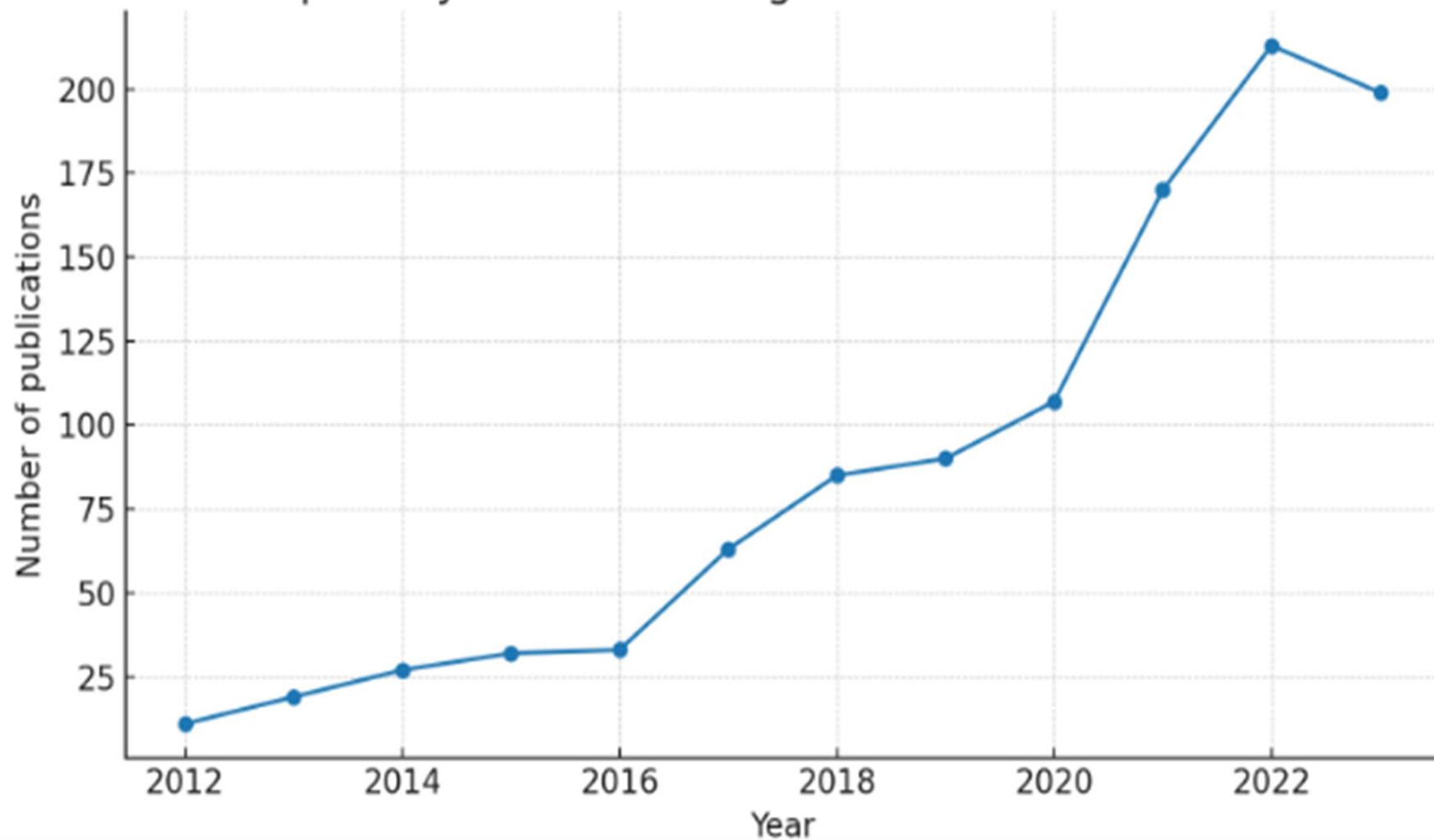
Source: ORCHA Health



MEDICAL DEVICE NETWORK

### Digital Mental Health Publications per Year (2012-2023)

Web of Science primary research on digital interventions for mental well-being

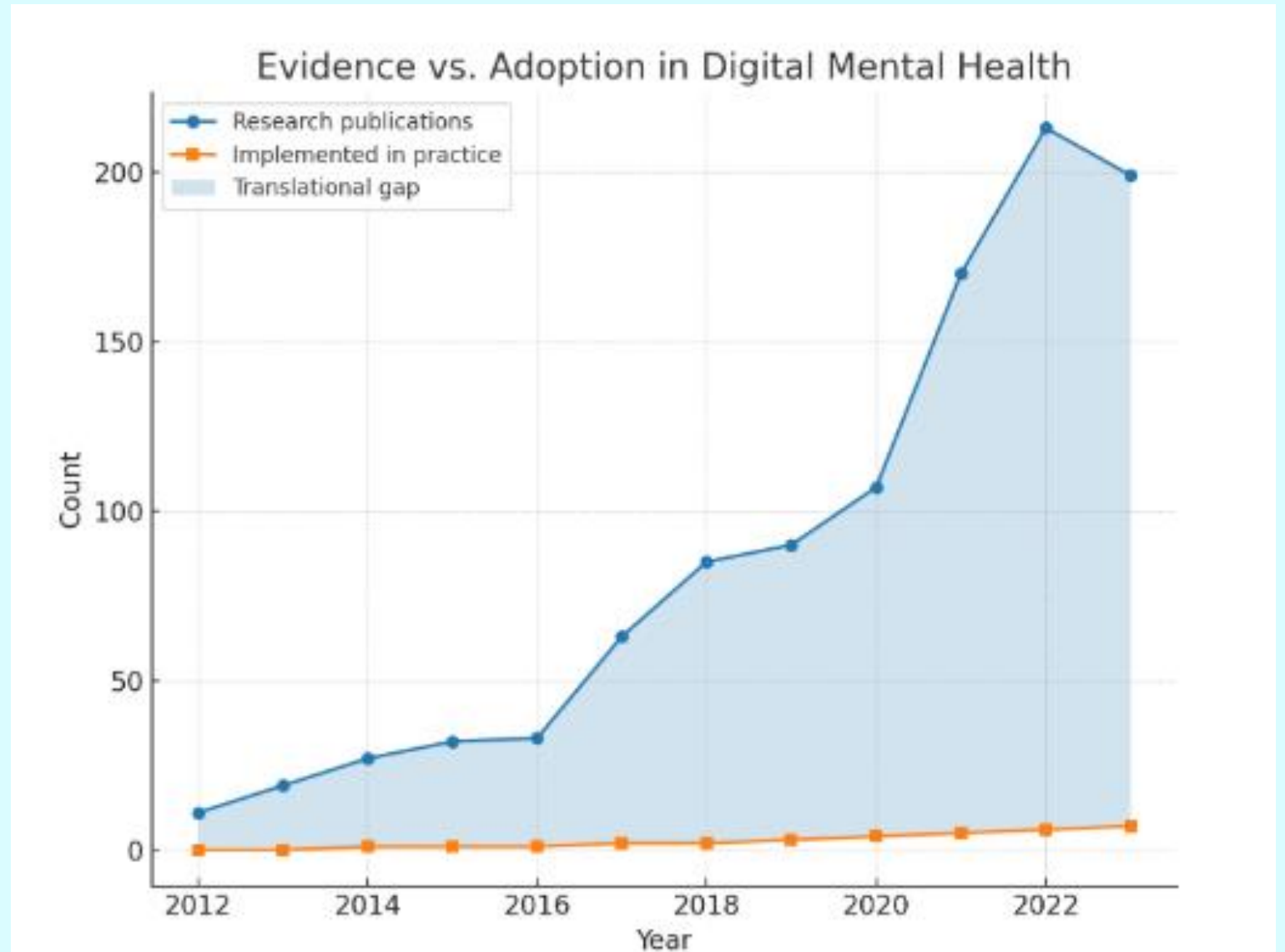


# The Promise of Digital Mental Health

- Variety
  - ✓ *web-based; smartphone apps, virtual reality, AI*
  - ✓ *blended vs standalone*
- Expanding access to care - scalability
- Flexibility
- Cost effectiveness
- Autonomy, ownership, agency
- Personalisation

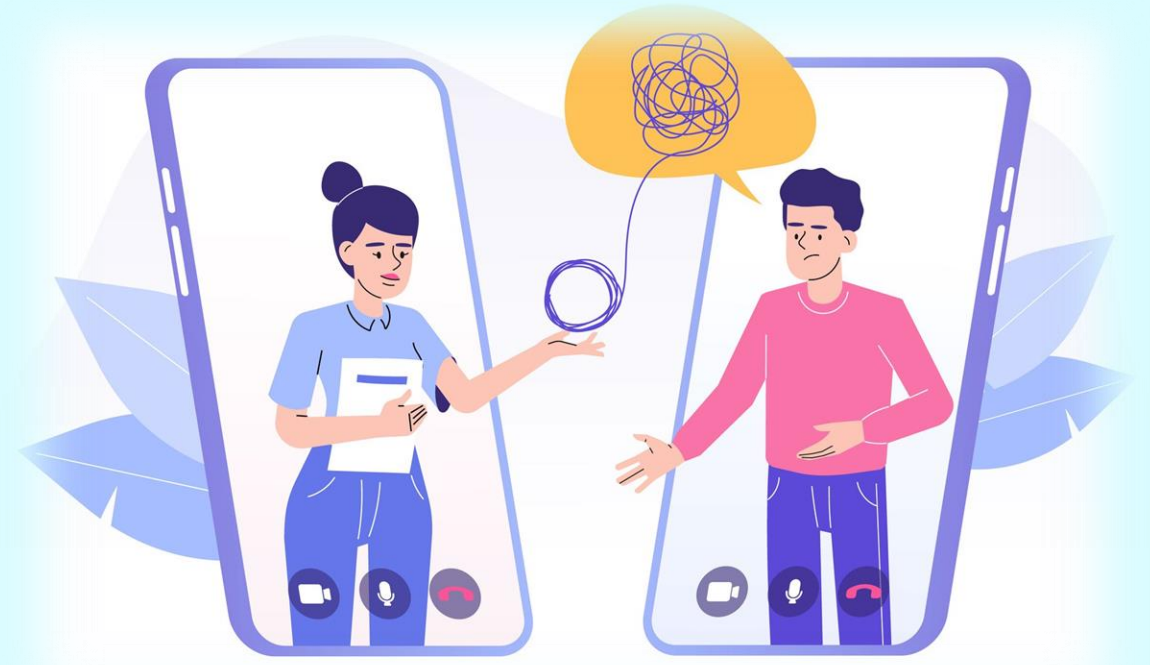


# The Translational Gap (UK)



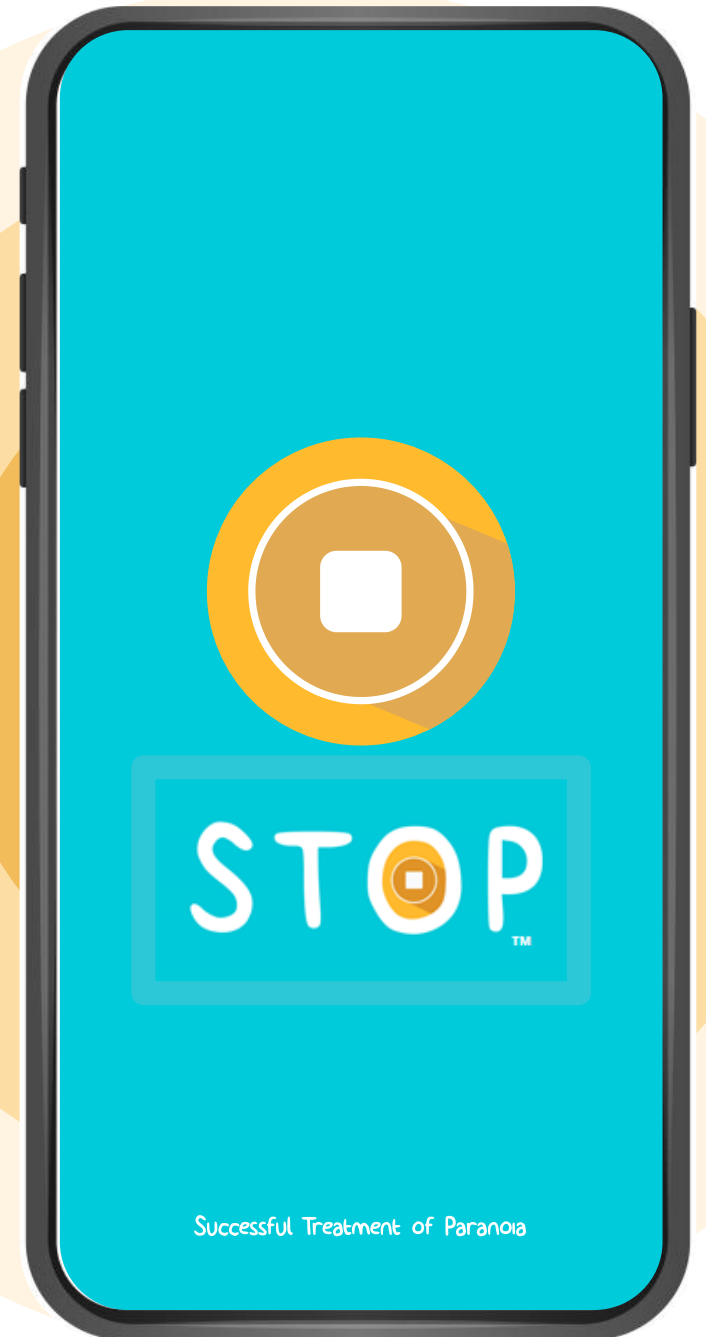
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# Successful Treatment Of Paranoia

“Calming suspicious minds”





# Paranoia

## What is it?

- Unjustified suspicion and mistrust of others or the world at large.

## Why create new treatments?

**>200 million** people globally experience paranoia-related symptoms.

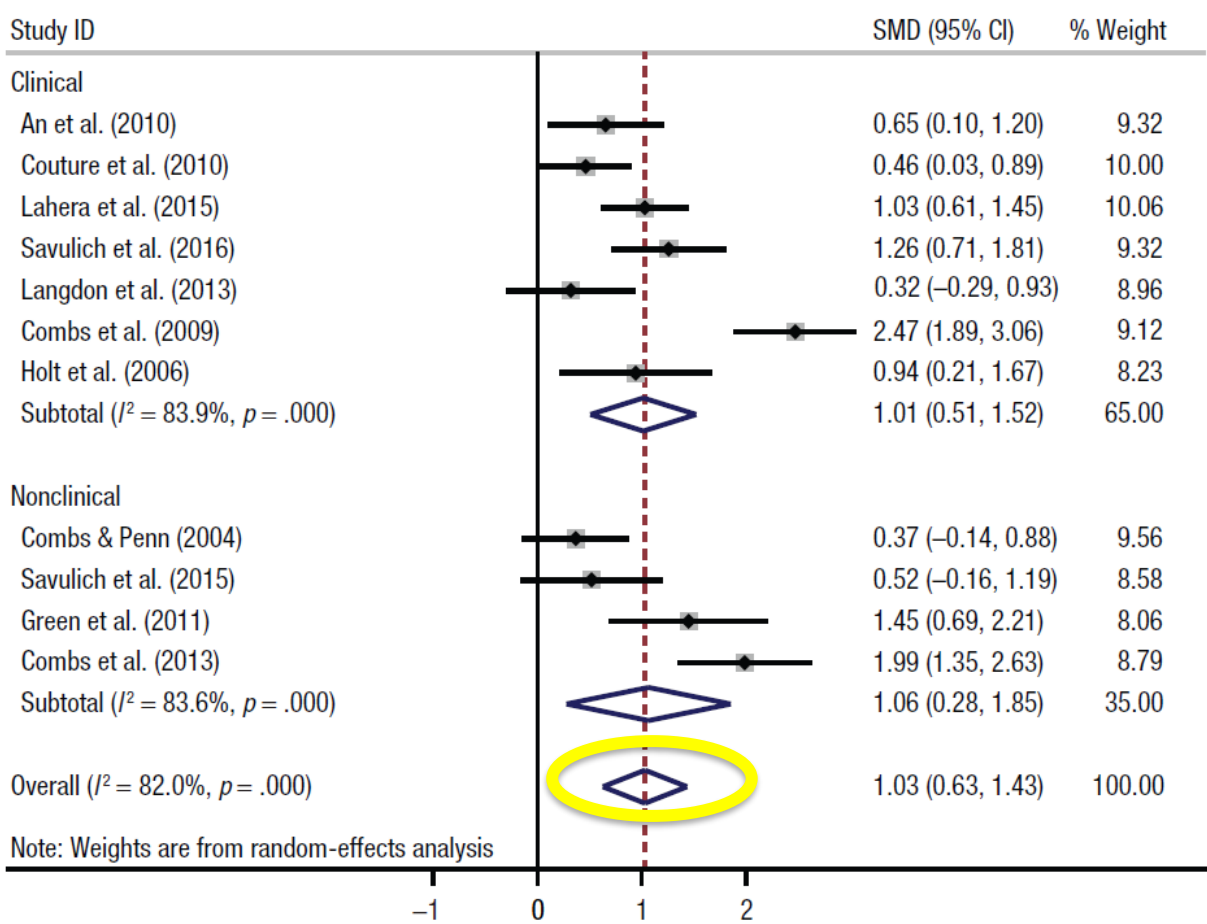
**Only 1 in 10** UK patients receive the recommended psychological therapy.

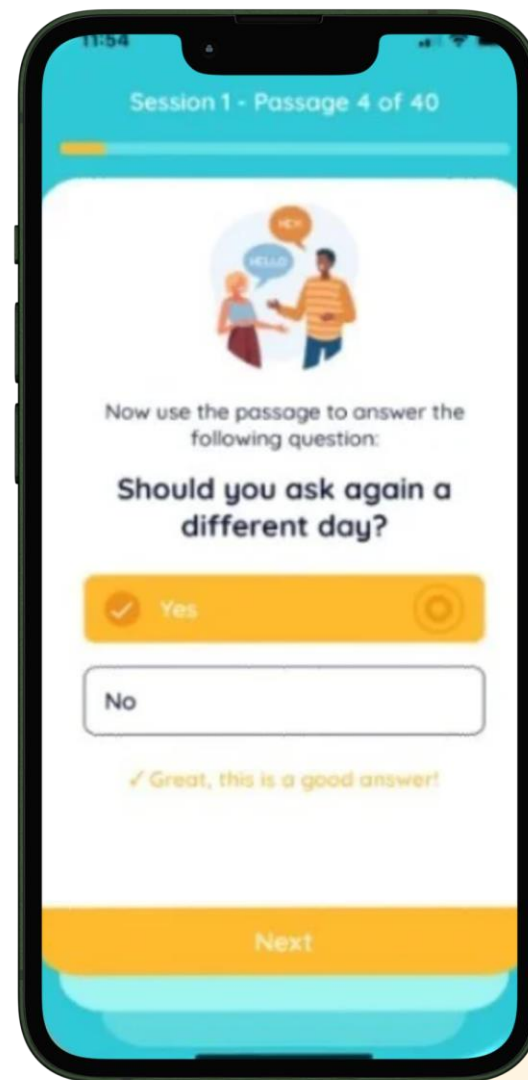
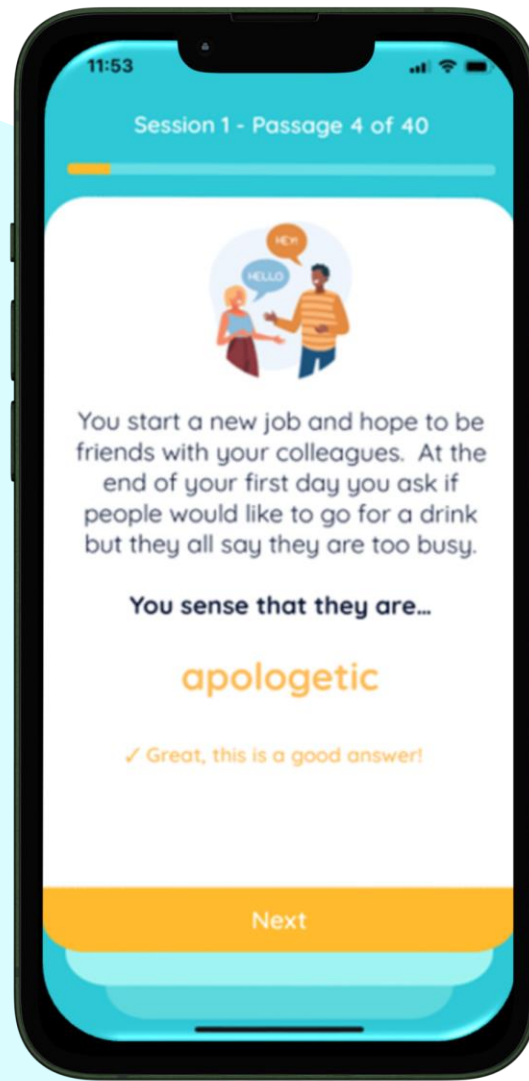
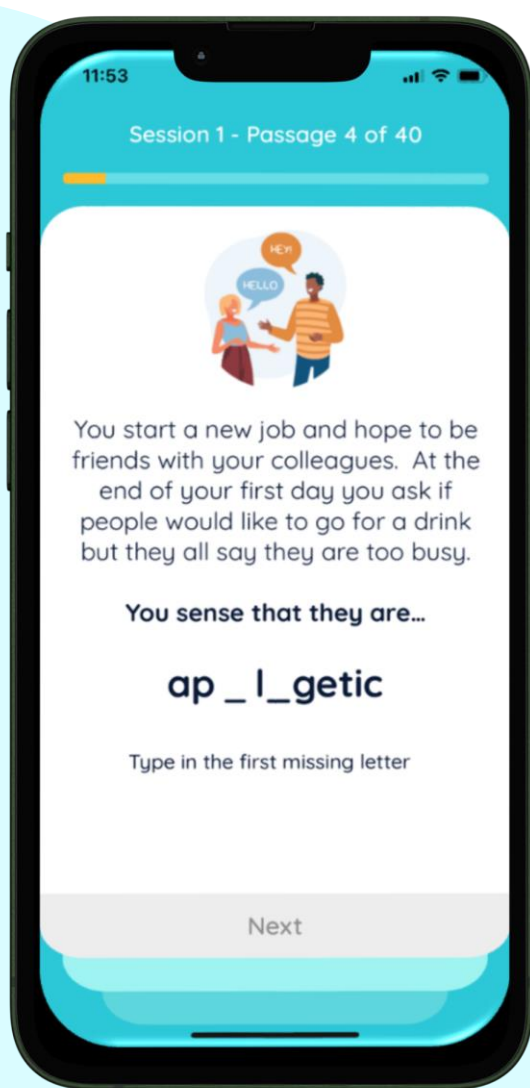
**Around 30%** continue to experience symptoms after treatment



# Interpretation Bias in Paranoia: A Systematic Review and Meta-Analysis

Trotta, Kang, Stahl & Yiend, 2021. Clinical Psychological Science 2021, Vol. 9(1) 3–23 <https://doi.org/10.1177/2167702620951552>







## Next Steps

1. Iteration (e.g. personalise, lengthen)
2. Health Economic data
3. Business model
4. Overseas feasibility

➤ Kings MedTech 2025

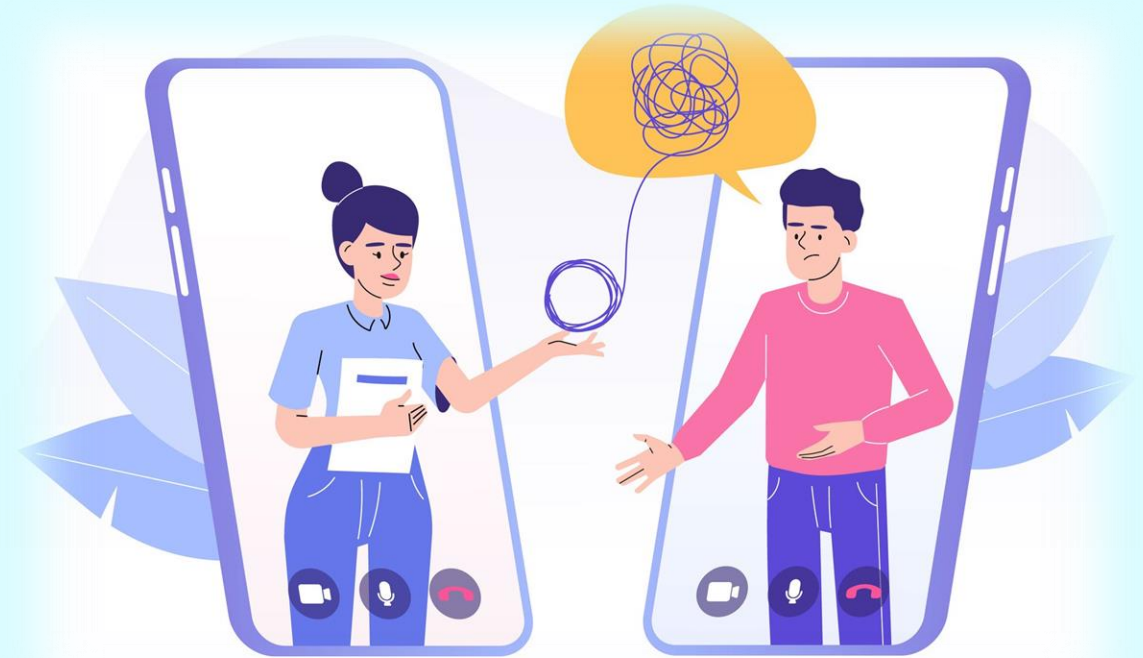
➤ Related products:





# Overview

- The Promise of Digital Mental Health
- Case Study: STOP (Successful Treatment of Paranoia)
- **Opportunities in the Digital Age**
  - *Co-production*
  - *Digital therapeutic alliance*
- Challenges
- Pathways Forward



# Co-production – STOP example



Alex  
Kenny

## Key Contributions

- **Co-applicants and co-authors**
- **Lived Experience Advisory Panel (LEAP) - members**
- **Supported study design, ethical approval, and recruitment**
- **Co-developed app content and therapeutic rationale**
- **Qualitative investigations**
  - lived experience using STOP
  - Destigmatisation of 'paranoia'

Published on 08.12.2023 in Vol 10 (2023)

DOI: 10.2196/45453

📄 Preprints (earlier versions) of this paper are available at <https://preprints.jmir.org/preprint/45453>, first published January 01, 2023.



## User-Centered Development of STOP (Successful Treatment for Paranoia): Material Development and Usability Testing for a Digital Therapeutic for Paranoia

Che-Wei Hsu<sup>1,2</sup> ; Daniel Stahl<sup>3</sup> ; Elias Mouchlianitis<sup>4</sup> ; Emmanuelle Peters<sup>5,6</sup> ; George Vamvakas<sup>3</sup> ; Jeroen Keppens<sup>7</sup> ; Miles Watson<sup>2</sup> ; Nora Schmidt<sup>2</sup> ; Pamela Jacobsen<sup>8</sup> ; Philip McGuire<sup>9</sup> ; Sukhi Shergill<sup>2</sup> ; Thomas Kabir<sup>9</sup> ; Tia Hirani<sup>2</sup> ; Ziyang Yang<sup>2</sup> ; Jenny Yiend<sup>2</sup>



- Twelve months' development
- User generated content (40 items - 40 min - x 12 sessions)
- Quantitatively & qualitatively evaluated by clinicians and users

# Digital Therapeutic Alliance

**Therapeutic alliance** is between a person seeking change and a “change agent” (Bordin’s pan-theoretical model of alliance)

Comprises:

1. Mutual goals
2. Mutually agreed tasks
3. Trust and confidence (bond)



Taylor et al. BMC Public Health (2025) 25:2450  
<https://doi.org/10.1186/s12889-025-23603-5>

BMC Public Health

RESEARCH

Open Access

How do users of a mental health app conceptualise digital therapeutic alliance? A qualitative study using the framework approach



Theresa Taylor<sup>1</sup>, Simon D'Alfonso<sup>2</sup>, Maria João Tralhão Dolan<sup>1</sup>, Jenny Yiend<sup>3</sup> and Pamela Jacobsen<sup>1\*</sup>



# Humanness (Theme 1)

“Sense of  
humour”  
Participant 6

"I did feel connected with the app because when I finished the trial and then you can't access [the app] anymore it was a bit like ohh I felt a bit of a loss." (Participant 12)

“Someone  
to talk to”  
Participant 9

“Made  
me  
smile”  
Participant 2

“friendly”  
Participant 3



# How is it to use the app (Theme 4)

“I never trusted the  
technical glitch I  
always thought this  
is deliberate.”  
(Participant 2)





# Flexibility enhances relationship (Theme 5)

"I've gotta really  
fight for [face to  
face therapy]  
whereas the app...  
it's my choice"  
(Participant 6)



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- Translational Research considerations in Mental Health?
- Case Study: STOP (Successful Treatment of Paranoia)
- Opportunities in the Digital Age
- **Challenges**
- Pathways Forward



Rank	Barrier	Why It's Critical
1	Engagement & adherence	Users often start but rapidly abandon, undermining impact
2	Perceived usefulness	Users need personally meaningful content to stay involved
3	Usability issues	Technical flaws frustrate users and disrupt usage
4	Privacy & trust concerns	Data fears drive opt-outs and scepticism
5	Poor healthcare integration	Tools not integrated into care paths & remain underutilised
6	Lack of evidence and policy support	Weak backing diminishes credibility and sustainability
7	Digital literacy & user capacity	Users with low skills or limited resources face access barriers
8	Lack of person-specific design	One-size-fits-all designs reduce relevance and acceptance

# Regulatory Challenges

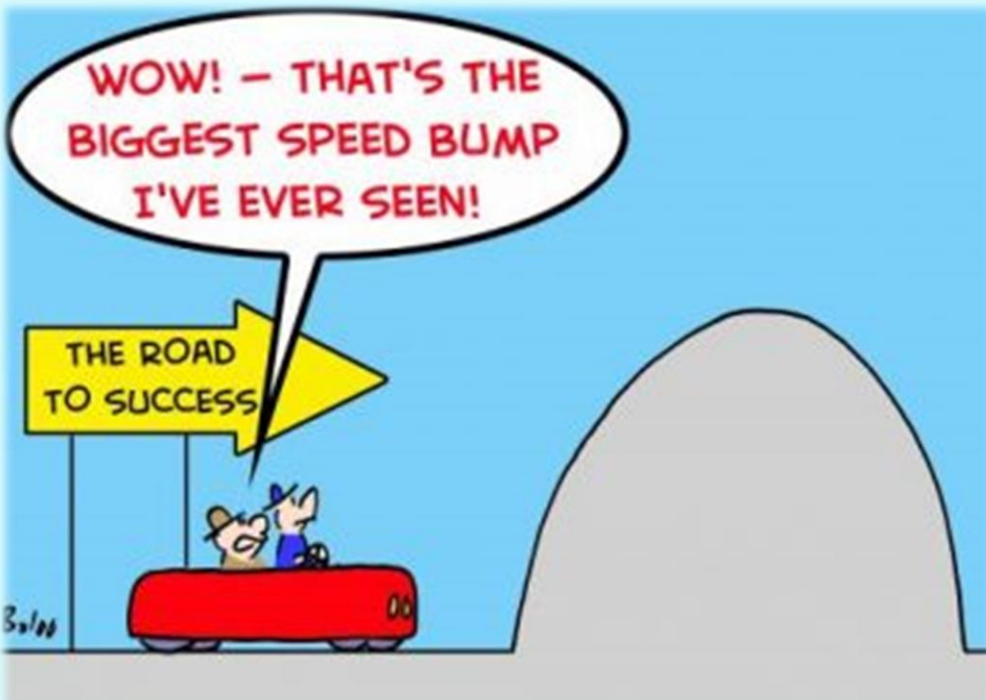
## ❑ Complex international standards



Standard / Guideline	Focus Area	Pages
IEC 62304	Software lifecycle and safety classification	81
ISO 14971	Risk management throughout product lifecycle	36
ISO 13485	Quality management systems for medical device manufacturing	60

## ❑ Significant paperwork

- Main Submission (Application; Protocol; Ethics Approval etc.): ~150–300 pages
- **Technical File (Core Dossier): ~400–800+ pages**
- Workload: Typical preparation **6–12 mths**



Taher et al. *Trials* (2024) 25:604  
<https://doi.org/10.1186/s13063-024-08421-1>


Trials

METHODOLOGY

Open Access



# Developing a process for assessing the safety of a digital mental health intervention and gaining regulatory approval: a case study and academic's guide

Rayan Taher<sup>1</sup>, Charlotte L. Hall<sup>2</sup>, Aislinn D Gomez Bergin<sup>2,3</sup>, Neha Gupta<sup>4</sup>, Clare Heaysman<sup>5</sup>, Pamela Jacobsen<sup>6</sup>, Thomas Kabir<sup>7</sup>, Nayan Kalnad<sup>4</sup>, Jeroen Keppens<sup>8</sup>, Che-Wei Hsu<sup>9</sup>, Philip McGuire<sup>10</sup>, Emmanuelle Peters<sup>11</sup>, Sukhi Shergill<sup>12</sup>, Daniel Stahl<sup>13</sup>, Ben Wensley Stock<sup>14</sup> and Jenny Yiend<sup>1\*</sup> 

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- Challenges
- **Pathways Forward**
  - Supportive Accountability & Digital Navigators
  - Governmental policy





# Supportive Accountability

- theoretical model guiding human support for eHealth interventions
- people (e.g. recovered peers) act as '**coaches**' after basic training
- non-clinical 'scaffolding':
  - promotes engagement (user is accountable to a trusted coach)
  - basic practical/technical assistance;
  - Safety/ signposting

JOURNAL OF MEDICAL INTERNET RESEARCH

## Viewpoint

### Supportive Accountability: A Model for Providing Human Support to Enhance Adherence to eHealth Interventions

David C Mohr<sup>1</sup>, PhD; Pim Cuijpers<sup>2\*</sup>, PhD; Kenneth Lehman<sup>1\*</sup>, PhD

<sup>1</sup>Department of Preventive Medicine, Northwestern University, Chicago, IL, United States

<sup>2</sup>Department of Psychology, Vrije Universiteit, Amsterdam, Netherlands

Mohr et al

## Digital Navigators

Acta Psychiatrica Scandinavica

Acta Psychiatr Scand 2020; 141: 350–355  
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DOI: 10.1111/acps.13149

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ACTA PSYCHIATRICA SCANDINAVICA

### From Research to Clinical Practice

## Digital navigators to implement smartphone and digital tools in care

Wisniewski H, Torous J. Digital navigators to implement smartphone and digital tools in care.

H. Wisniewski, J. Torous 

# Digital innovation is front and centre:

*“Reshaped innovation strategy”*

*“faster, risk proportionate and more predictable routes to market”*

*“HealthStore..[will] enable patients to access approved digital tools ....”*

*“from bricks to clicks”*

*“..speeding up clinical trials, future-proofing our regulatory landscape, streamlining procurement and accelerating adoption and spread...”*

*“a more permissive operating model that allows innovators to thrive..”*



[www.gov.uk/government/publications/10-year-health-plan-for-england-fit-for-the-future](https://www.gov.uk/government/publications/10-year-health-plan-for-england-fit-for-the-future)



# Key Take Home Messages

## The Promise

- Digital therapy is here to stay
- It's flexible, cost effective & accessible
- Supports self-management & complements professional therapy

## Case Study: STOP

- Holds promise
- Make it longer

## Opportunities

- Genuine co-production
- Digital Alliance

## Challenges

- Many current barriers to adoption
- Plan for regulation

## Pathways Forward

- Create digital navigators
- Governmental policies

# Questions?

**Professor Jenny Yiend and.....**

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Stahl, Daniel  
Taher, Rayan  
Teale, Ashley  
Vamvakas, George

# Participants

## Inclusion Criteria

- Experiencing distressing paranoia for at least the past month
- English
- Negative interpretation bias
- Stable on medication (+3 months)
- Capacity to consent
- Over 18 years old

## Exclusion Criteria

- Receiving similar psychological intervention
- Currently or planning to take part in other interventional research study
- Cognitive impairment
- Significant physical illness
- Major substance or alcohol misuse
- Experiencing 'extreme' paranoia
- At high risk of suicide

# Treatment Adherence



**Adherence** was defined by two criteria:

**1.Session completion:** Responding to  $\geq 75\%$  of trials per session

**2.Dose completion:** Completing  $\geq 6$  sessions or  $\geq 50\%$  of total sessions (whichever is lower)

- The predefined adherence target (meeting both 1 and 2 above) was 75%.

**85%** of participants (232/274) met adherence criteria.