The PSYLECT study
opportunities and pitfalls of digitizing a clinical trial in a LMIC

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Disclosure

- I have no conflicts of interest regarding the topics of this presentation.

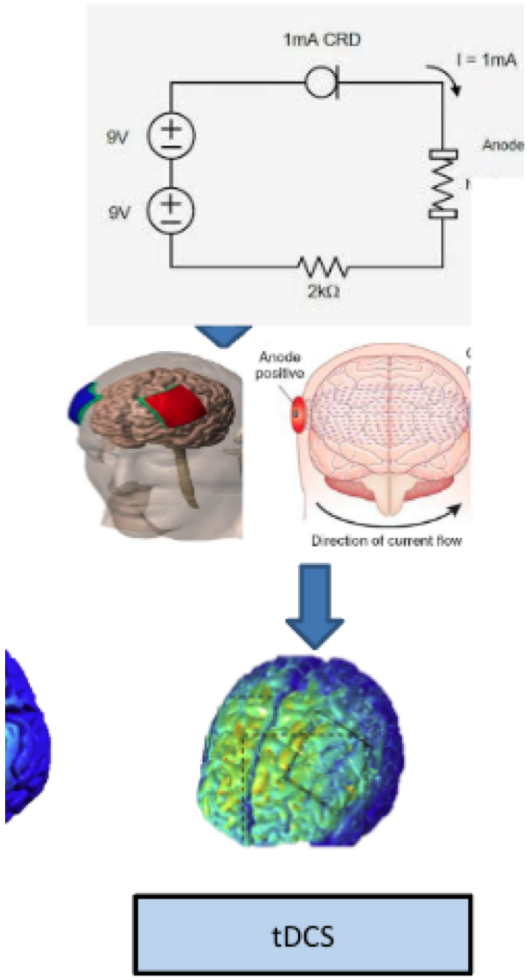
Outline

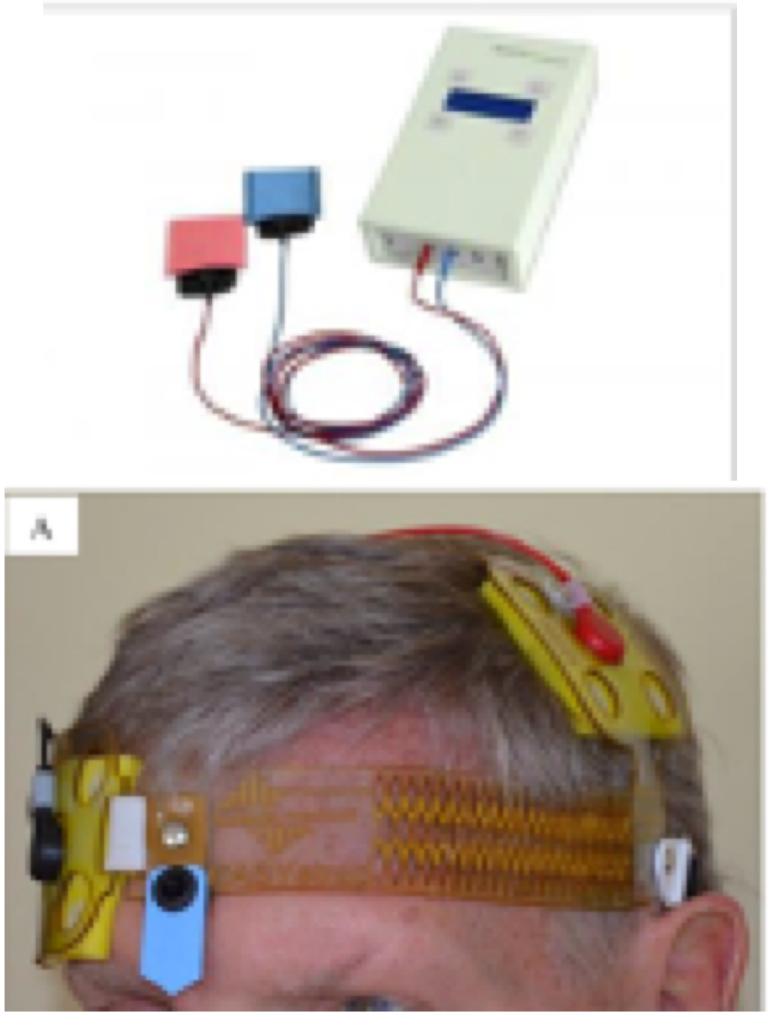
- The Psylect clinical trial: background and rationale
- Digitalization and ethical challenges

Major Depressive Disorder

- High prevalence
- Responsible for the main burden of all mental disorders
- Presents high rates of treatment resistance
- Interventions have low scalability

Transcranial direct current stimulation





The ELECT-TDCS trial

Brunoni et al., NEJM, 2017

PATIENTS

- 245 patients, 18-65 years
- HDRS $_{17}$ > 17
- No ADs at baseline

INTERVENTIONS

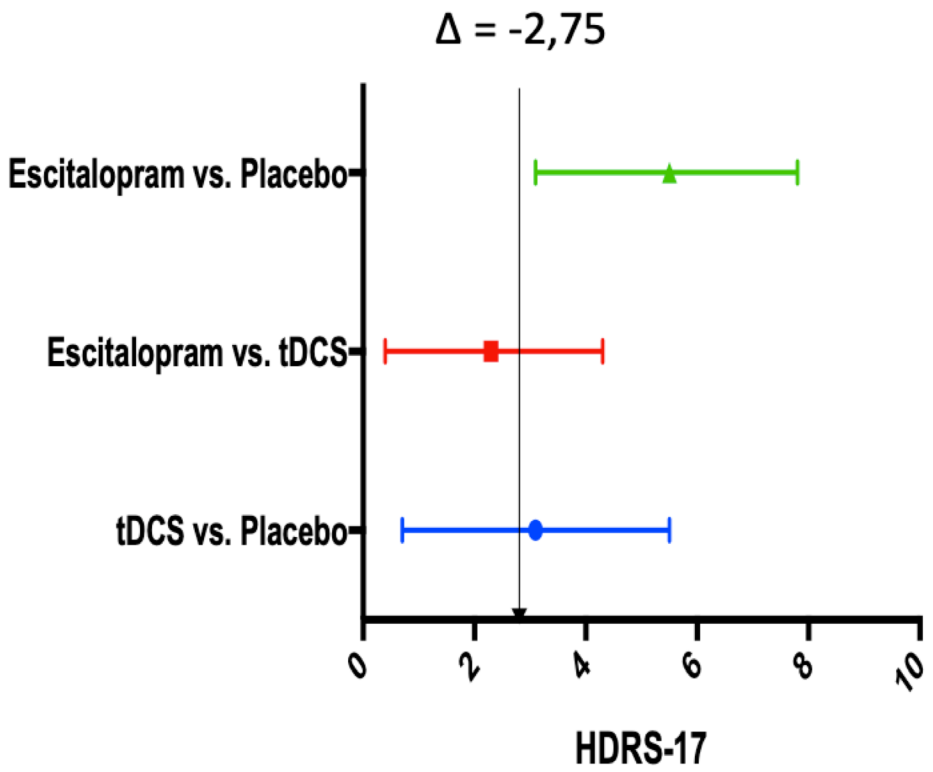
- Escitalopram 20 mg/day.
- 22 tDCS sessions
- **DESIGN**

Non-inferiority design with placebo group

Active tDCS
Placebo pill

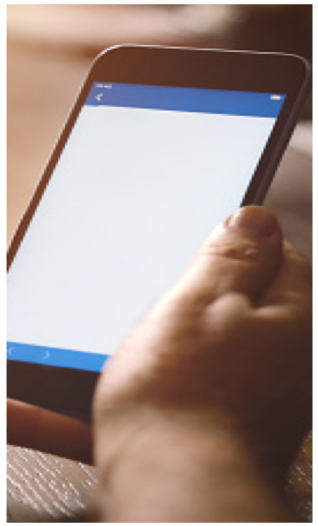
Sham tDCS
Escitalopram

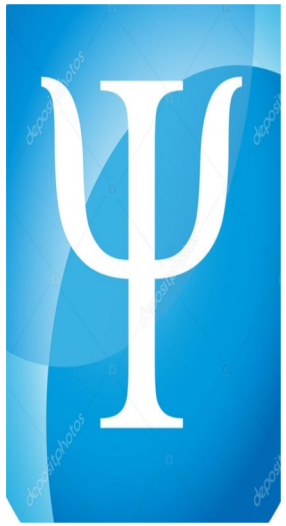
Sham tDCS
Placebo pill

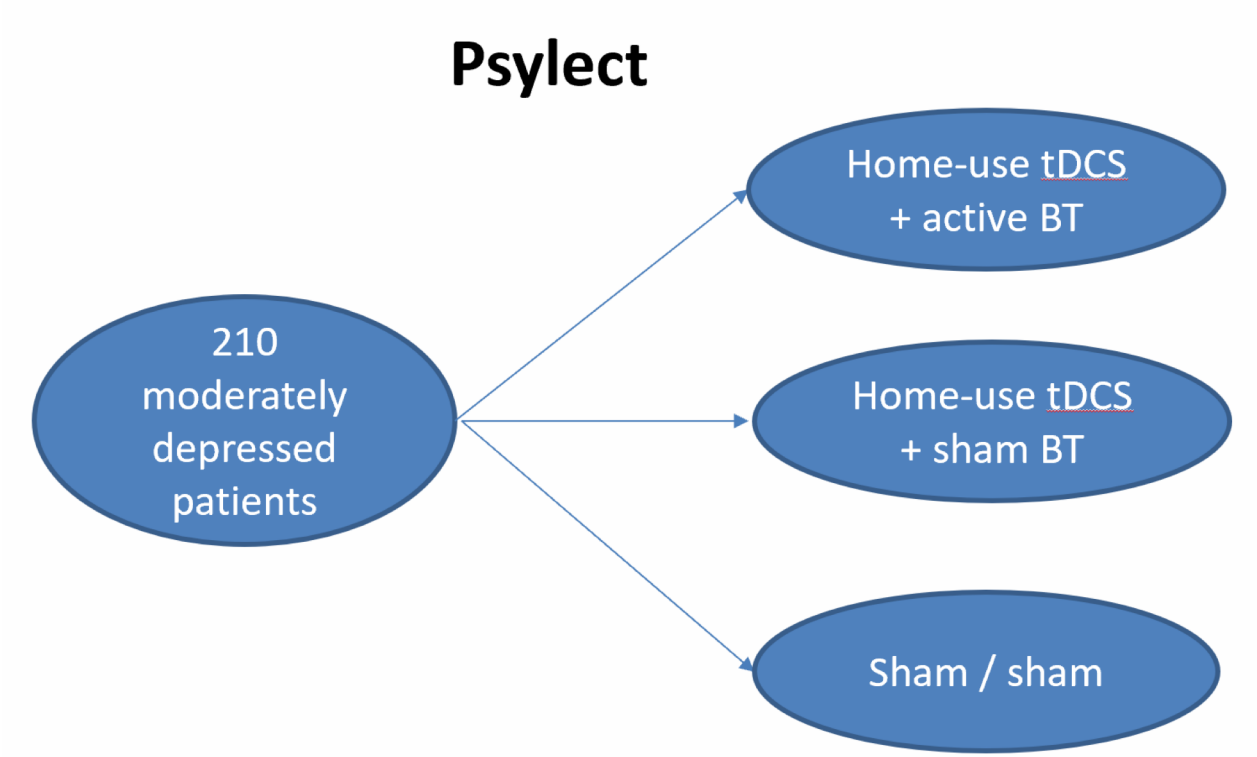


Escitalopram > tDCS > placebo

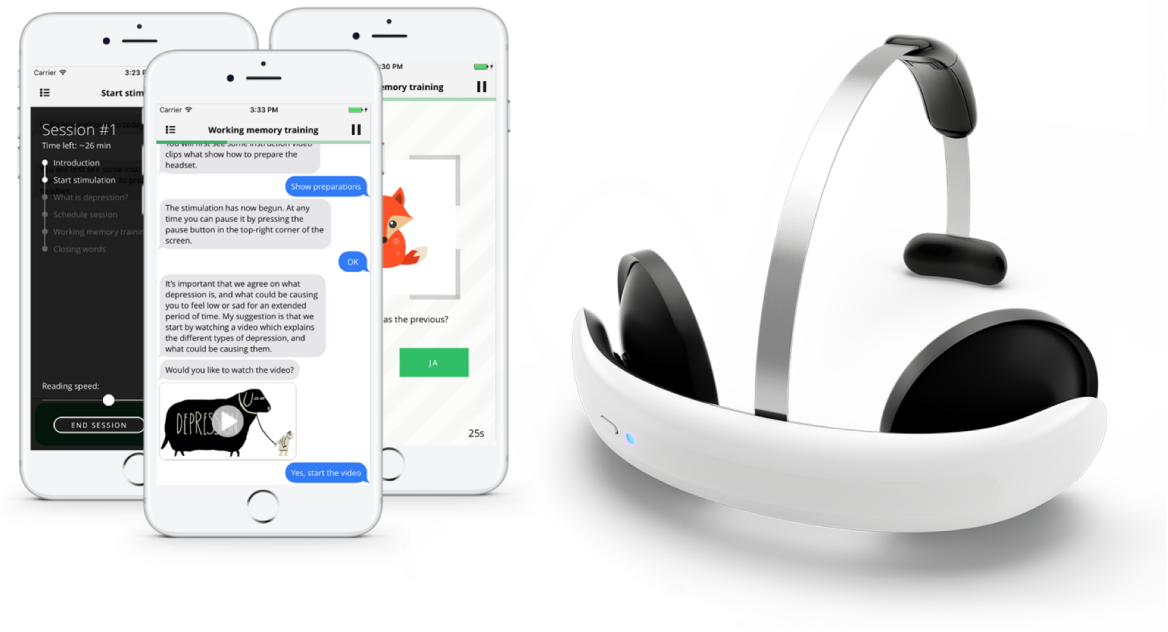
Psylect






Psylect
210 moderately depressed patients
Home-use tDCS + active BT
Home-use tDCS + sham BT
Sham / sham

Internet-based therapy with behavioural components



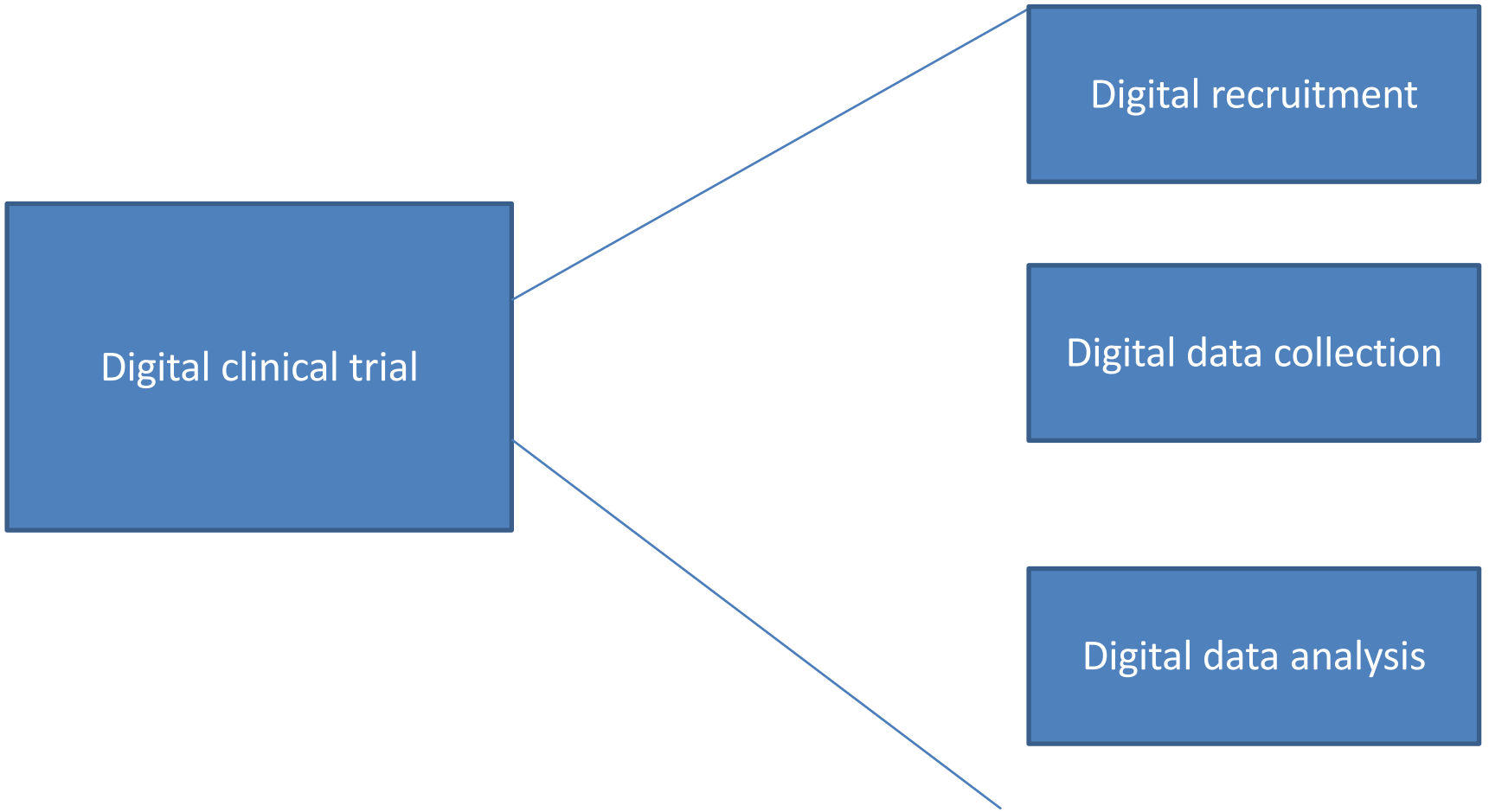
- Behavioural activation
- Meditation
- Physical activities
- Healthy diet
- Sleep hygiene
- Psychoeducation

PERSPECTIVE OPEN

Digitizing clinical trials

Nature Digital Health, 2020

O. T. Inan[1] ✉, P. Tenaerts[2], S. A. Prindiville[3], H. R. Reynolds[4], D. S. Dizon[5], K. Cooper-Arnold[6,21], M. Turakhia[7], M. J. Pletcher[8], K. L. Preston[9], H. M. Krumholz[10,11,12], B. M. Marlin[13], K. D. Mandl[14], P. Klasnja[15], B. Spring[16], E. Iturriaga[17], R. Campo[17], P. Desvigne-Nickens[17], Y. Rosenberg[17], S. R. Steinhubl[18] and R. M. Califf[19,20]



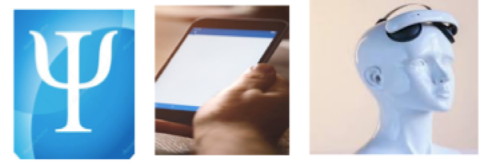
The PSYLECT trial

A digital trial

Recruitment

Screening

Interventions



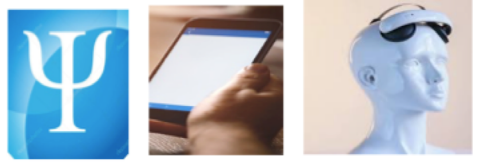
Data Collection / Analysis

The PSYLECT trial

A digital trial

Screening

Interventions



Data Collection / Analysis

Non-Maleficence

Onsite

Inclusion / exclusion

Online

Inclusion / exclusion

Digital exclusion

Machine learning

The PSYLECT trial

A digital trial

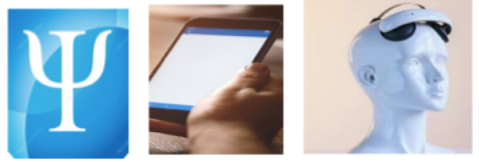
ADDITIONAL INFORMED CONSENT

Recruitment

Screening

INFORMED CONSENT

Interventions



Data Collection / Analysis

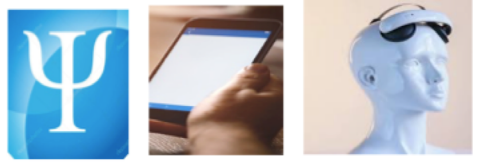
The PSYLECT trial

A digital trial

Recruitment

Screening

Interventions



Data Collection / Analysis

Justice

- Only people who can use digital devices can participate in the study. Again, a “digital exclusion” might occur.

- On the other hand, accessibility is expanded by mitigating daily commutes to/from the clinical centers. Also, this allows that the treatment occurs in non-business hours.

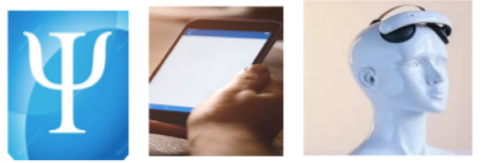
The PSYLECT trial

A digital trial

Recruitment

Screening

Interventions



Data Collection / Analysis

Lower standard-of-care

- Participants can send messages to the clinical trial team.

- However, answering questions 24/7 imposes a high burden to the team.

- Developing chatbots for simple questions (the most common ones) would help logistically, but could this decrease the standard of care?

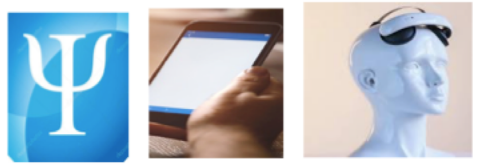
The PSYLECT trial

A digital trial

Recruitment

Screening

Interventions



Data Collection / Analysis

Autonomy

- The bioethical principle of autonomy has been discussed for a long time in vulnerable populations such as those with mental disorders.

- Digital studies might collect lots of sensitive data such as information related to mental health, further exposing these patients.

Accountability

Use of portable mobile Health device can lead to misuse, unitentionally or not, overuse, lack of training or device malfunctioning.

Who is accountable in these cases?

Conclusion

With great power

comes great(er) responsabilities

Muito obrigado!

(thank you very much)

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