

mHealth and Research Synergies and Controversies

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Patient empowerment

Support of behavior change

Self-care support

Easy access to information

Better diagnosis

Individualized and adaptive therapy

Remote care/telemedicine

**Offers from
digital
health**

Connected healthcare

Easier Communication

Reduced documentation burden

New insights due to big data and AI

Active & passive data collection

Scalability

Product and process optimization

Real-world data



Understanding the quality, effectiveness and attributes of top-rated smartphone health apps

Hannah Wisniewski,¹ Gang Liu,² Philip Henson,¹ Aditya Vaidyam,¹
Narissa Karima Hajratalli,³ Jukka-Pekka Onnela,² John Torous¹

Highly Rated Health Apps¹

Depression, anxiety, schizophrenia, addiction, diabetes, hypertension

120 highly rated apps

Non had FDA approval, but 50% made "medical claims"

It was not possible to identify a care set of features that were associated with the ratings of the app

Evidence Level in Clinical Research

Level

- 1 Systemat. review of RCTs, single RCT
- 2 Systemat. review of cohort studies, single cohort studies
- 3 Systemat. review of case-control studies, single case-control study
- 4 Case reports
- 5 Expert opinion

Research on apps

Over 300,000 Health related Apps¹

599 RCTs in PubMed²

90 App-based RCTs for a disease³

¹Wisniewski H et al.. Evid Based Ment Health 2019

²PubMed search for clinical trials 25.10.2008
(Mobile App OR smartphone APP) AND
(Randomized Controlled Trial OR RCT)

³Ongoing systematic review

Challenges

Patient	Often feasibility studies Small sample	=>	No clear conclusion regarding efficacy or effectiveness
Intervention	Complex interventions	=>	Active component? Multidisciplinary teams
	Complex technical infrastructure		Multidisciplinary team and different cultures (researchers, engineers)
	Onsite study implementation vs. remote access to app in real life	=>	External validity
Control	Digital or analog?	=>	Digital placebo effect?
Outcome	Fast technical development	=>	No time for establishment of standards
	Follow-up time short	=>	Validity of results
	Follow-up time long	=>	Results less meaningful because of technological advances

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**Our recent
research**

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Mobile health RCT's since 2011

- menstrual pain,
- chronic neck
- chronic back pain
- cancer related distress

Blödt et al. *Trials* 2014, 15:490
<http://www.trialsjournal.com/content/15/1/490>



STUDY PROTOCOL Open Access

Effectiveness of app-based relaxation for patients with chronic low back pain (Relaxback) and chronic neck pain (Relaxneck): study protocol for two randomized pragmatic

Original Research

ajog.org

Susanne Blödt¹, Daniel Pach¹, Stephanie Roll¹ and

GYNECOLOGY

Effectiveness of app-based self-acupressure for women with menstrual pain compared to usual care: a randomized pragmatic trial



Susanne Blödt, PhD¹; Daniel Pach, MD¹; Sanna von Esenhart-Rothe; Fabian Lotz; Stephanie Roll, PhD; Katja Icke; Claudia M. Witt, MD, MBA

JMIR MHEALTH AND UHEALTH

Mikolasek et al

Original Paper

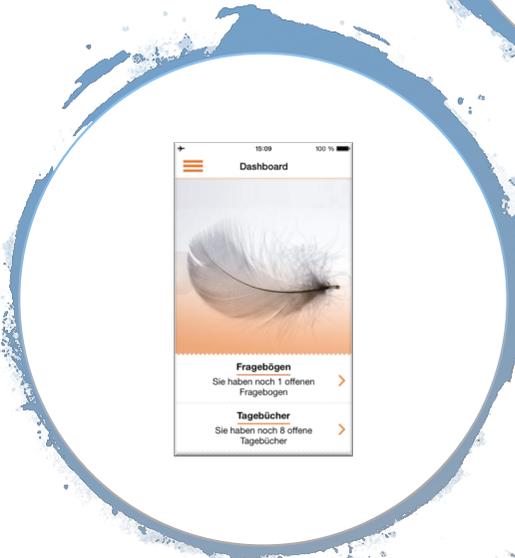
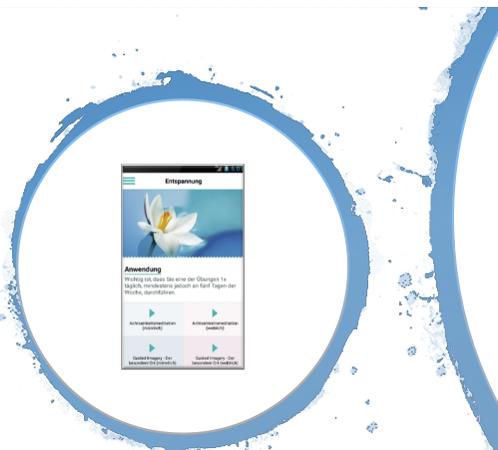
Adherence to a Mindfulness and Relaxation Self-Care App for Cancer Patients: Mixed-Methods Feasibility Study

Michael Mikolasek¹, MSc; Claudia M Witt^{1,2,3}, MBA, MD; Jürgen Barth¹, PhD

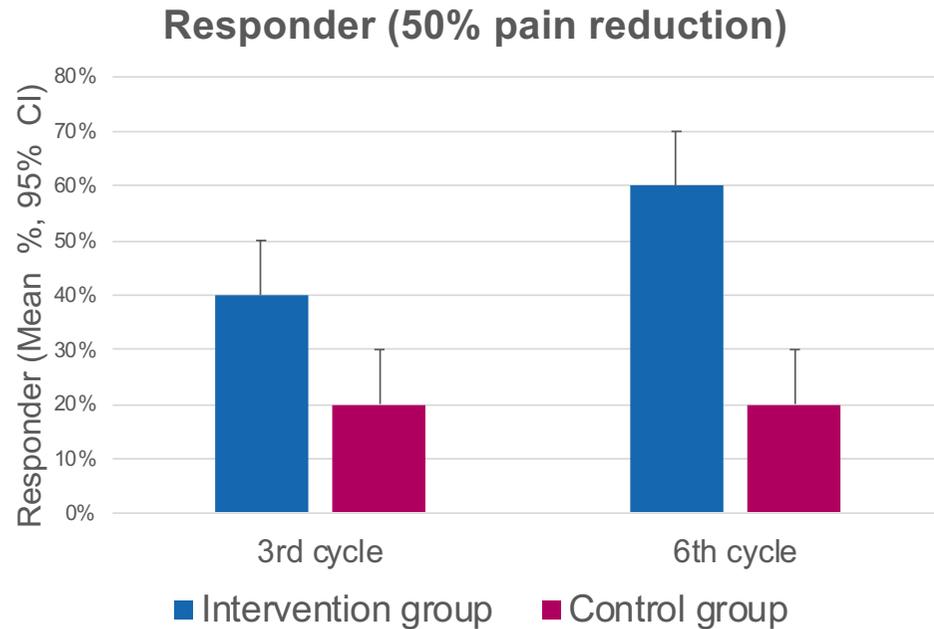
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³Center for Integrative Medicine, University of Maryland School of Medicine, Baltimore, MD, United States



Smartphone-App AKUD for menstrual pain



Original Research

ajog.org

GYNECOLOGY

Effectiveness of app-based self-acupressure for women with menstrual pain compared to usual care: a randomized pragmatic trial



Susanne Blödt, PhD¹; Daniel Pach, MD¹; Sanna von Eisenhart-Rothe; Fabian Lotz; Stephanie Roll, PhD; Katja Icke; Claudia M. Witt, MD, MBA



Altmetric

Hamburger Abendblatt

BERLIN

Studie: Selbstakupressur reduziert Regelschmerzen

freundin MODE BEAUTY FRISUREN KOCHEN & DIÄT LIEBE LIFESTYLE HOROSKOP VIDEOS ABO

Studie: Dieser einfache Trick hilft gegen Periodenschmerzen

Business Standard

This app may relieve you from menstrual cramps

App technologically outdated after study end

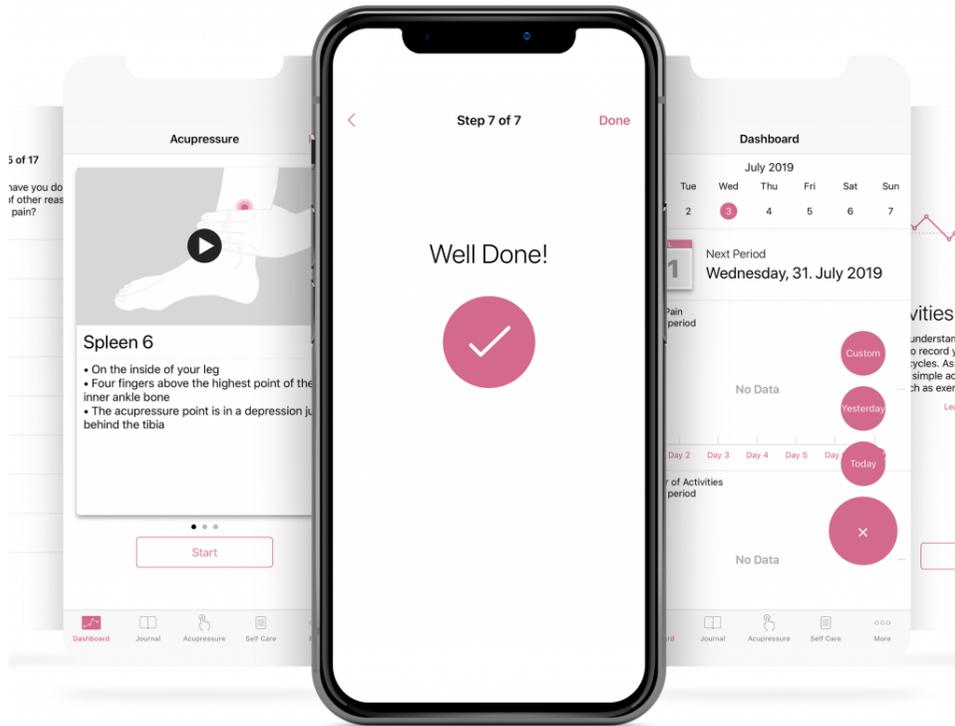
Data collection from 2012 to 2015

Publication of results in 2017

Meanwhile:

- change of iOS design paradigms
- new Apple user interface guidelines
- new frameworks
- new programming language SWIFT etc.
- General Data Protection Regulation

App-based self-care for menstrual pain: a new research app



Preprint

An international ResearchKit app-based pragmatic randomized control trial for women with menstrual pain (primary dysmenorrhea): development, access and engagement

Jiani Wang; Alizé A. Rogge; Mike Armour; Caroline A. Smith; Christopher R. D'Adamo; Claudia R. Pischke; Hung-Rong Yen; Mei-Yao Wu; Ari Ojeda Ocampo Moré; Claudia M. Witt; Daniel Pach

594 women (age 18-34) with menstrual pain

3 Groups:

- complete app
- app without self-acupressure feature
- app without self-care information

ResearchKit

Remote recruitment

Anonymous data collection

General challenges

- Communication with developers challenging (different culture, different language)
- Development and support for different platforms (e.g. iOS and Android) difficult
- Behavior change techniques became very important (definition of dialogues, descriptions, reminders etc.)
- Great care for privacy at any step
- Complex project management in a new field with many decisions during development phase
- Study nurses have to learn new technologies

App trial controversies

- Development of the app impacted the intervention and the study design
- Technical description of the app was already needed during the approval process of the study (IRB and data protection officer)
- Long development times for apps
- App setting impacted choice of outcomes / outcome validity
 - NRS instead of VAS
 - Less outcomes
 - Questions more frequently

Future challenges

How to increase speed of trials

Path of future technical development not clear

New EU medical device regulation in 2020:

- More documentation
- Classification of apps more strict
- Intended purpose (treatment or diagnose?) => medical device => Konformitätsbewertungsverfahren (based on classification)
- Manufacturer needs quality management system

Privacy

„Digitale-Versorgung-Gesetz“ - DVG in Germany

- Potential reimbursement of digital health apps
- App have to show “usefulness” in a short time
- More focus on evidence

Clinical research in mHealth is feasible!

Time is key and trial regulations influence this negatively



Tagungen &
Veranstaltungen

aktuell

Chronisch krank in der digitalen Welt

Save the date
25. März 2020

12.00–17.45 Uhr
Careum Weiterbildung
Aarau