cachet | Copenhagen Center for Health Technology

CACHET Unified Methodology for Assessment of Clinical Feasibility

Jakob E. Bardram
director, professor, MSc, PhD

Professor in computer science
Technical University of Denmark

Adjunct professor in public health
University of Copenhagen

Technical University of Denmark DTU | REGION H | The Capital Region of Denmark | CITY OF COPENHAGEN | UNIVERSITY OF COPENHAGEN

Design Research in Healthcare

- Methodologically, the design of health technology, sits at the intersection of
  - the design sciences
  - the clinical sciences.
- Design science
  - designed, developed, evaluated, and refined in a experimental process,
  - relying on modern iterative and user-centered design methodologies.
- Health / Clinical science
  - clinically verified
  - assessment of clinical safety, efficacy, and effectiveness

cachet | Copenhagen Center for Health Technology

Problems with RCTs... (from a tech perspective)

- **Rigid**
  - experiments are not allowed
  - does not allow for improvements/changes during trial
  - technology is hard to keep constant
- **Resource demanding**
  - N seems unreasonable large
  - T is very long – technology is outdated during the trial
  - costs a lot of $$$
- **Black Boxing**
  - everybody seems blind
  - can't investigate what works and what doesn't
  - can't test different alternatives (A/B testing)
  - can't get user input for (improving) design

cachet | Copenhagen Center for Health Technology

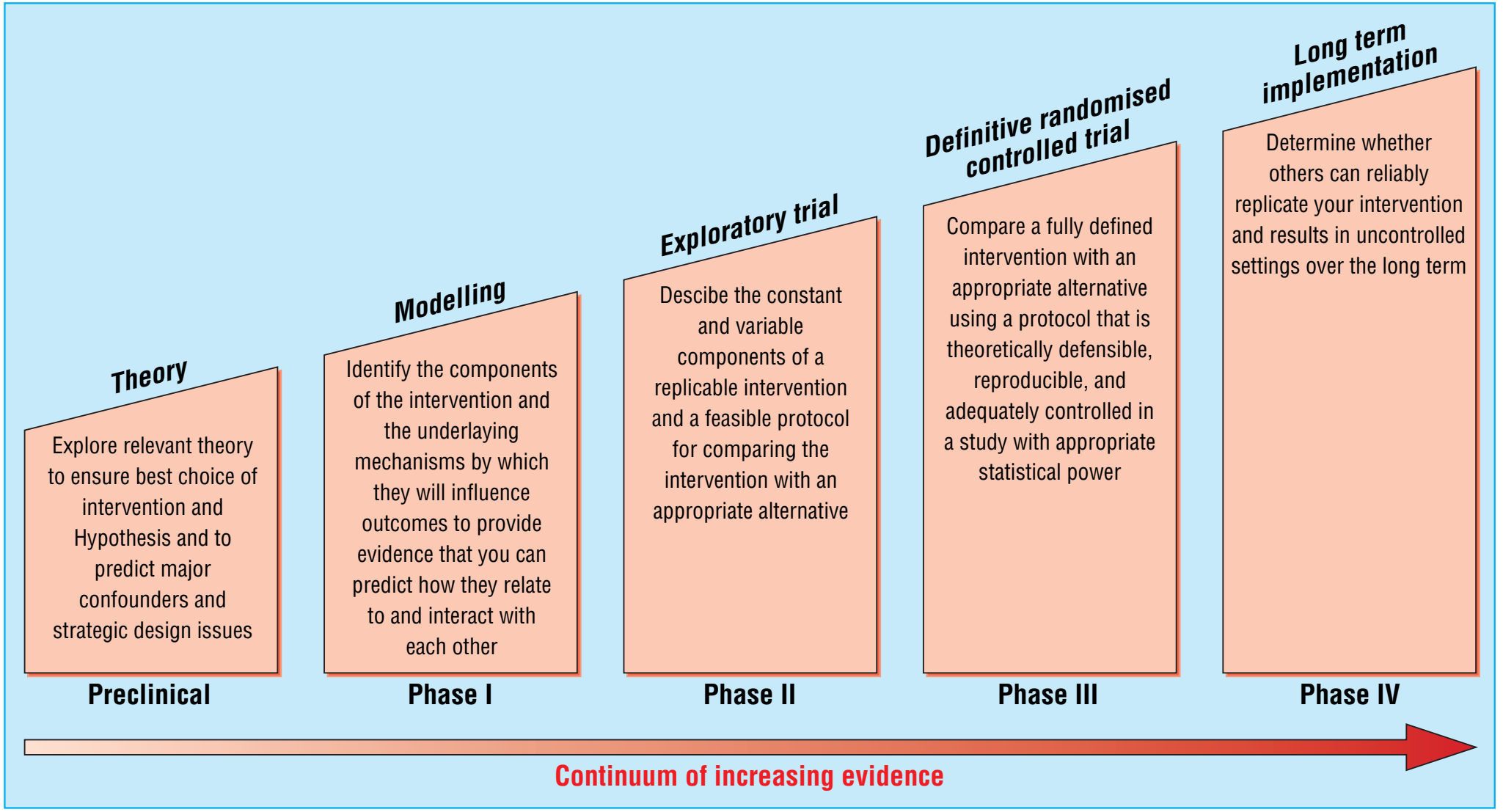


Fig 1 Sequential phases of developing randomised controlled trials of complex interventions

Campbell M, Fitzpatrick R, Haines A, et al. Framework for design and evaluation of complex interventions to improve health. *BMJ*. 2000;321(7262):694-696.

cachet | Copenhagen Center for Health Technology

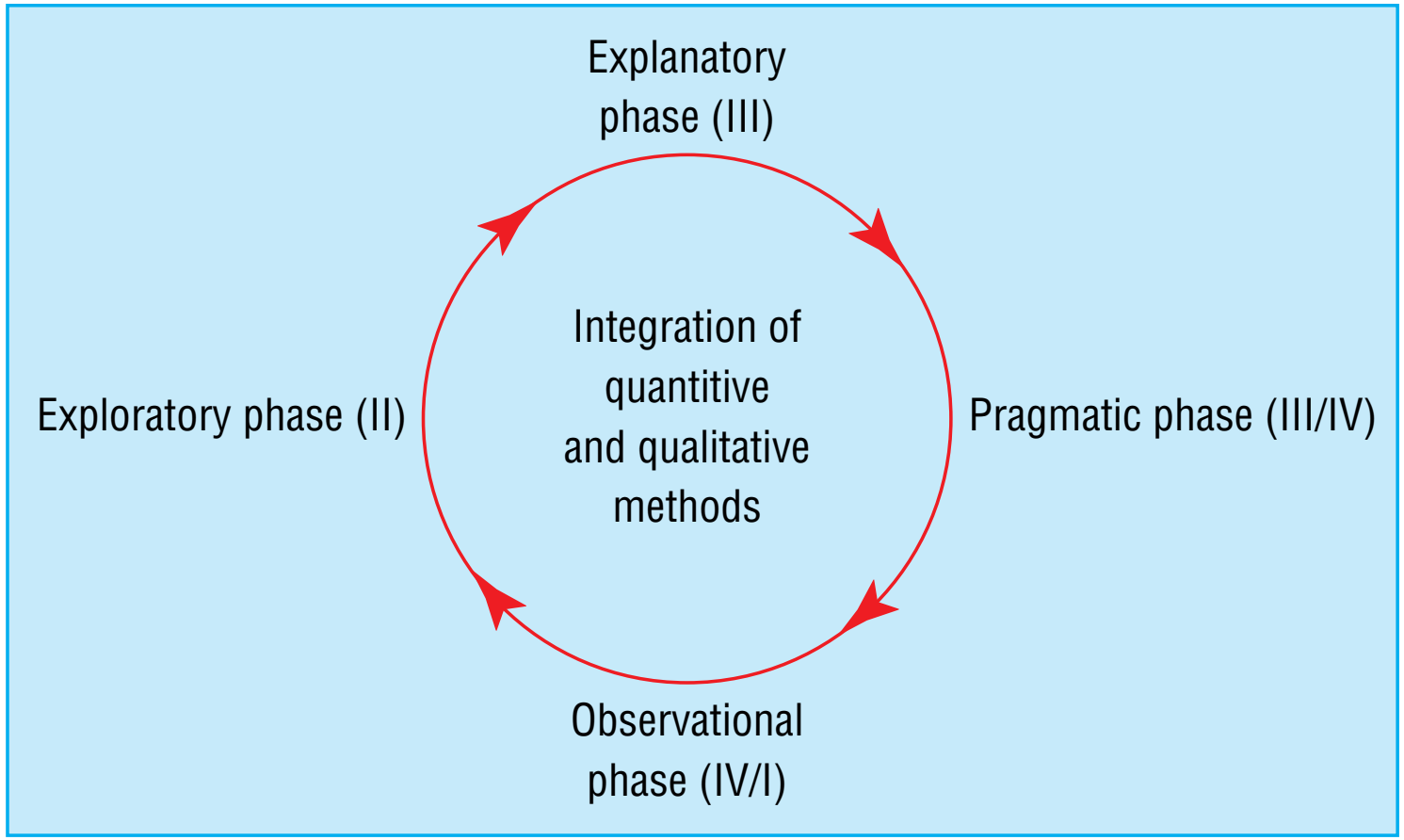
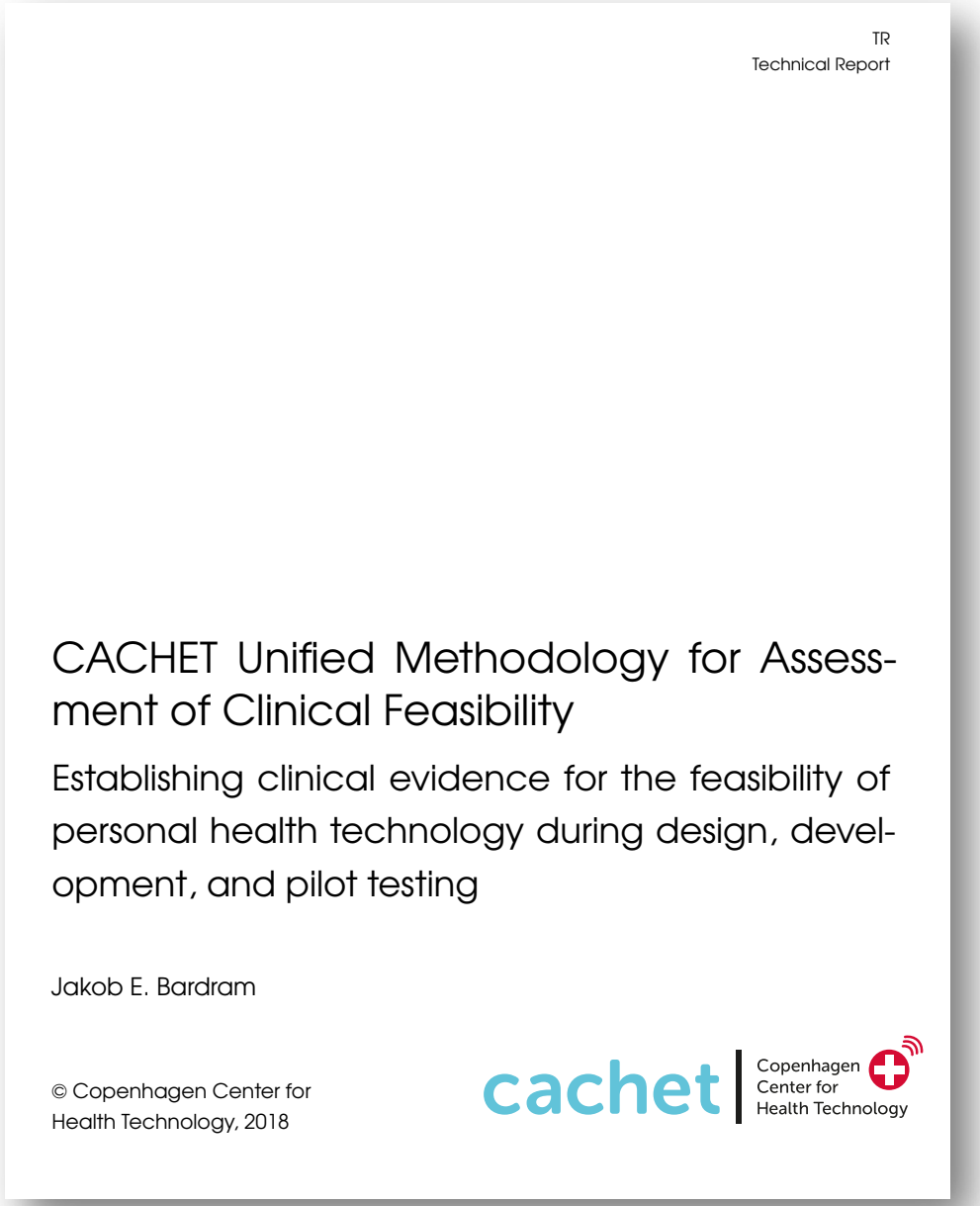


Fig 2 Iterative view of development of randomised controlled trials of complex interventions

Campbell M, Fitzpatrick R, Haines A, et al. Framework for design and evaluation of complex interventions to improve health. *BMJ*. 2000;321(7262):694-696.



#1 – User Adoption

#2 – Perceived Usefulness & Usability

#3 – Health Efficacy

Jakob E. Bardram. *CACHET Unified Methodology for Assessment of Clinical Feasibility*. Technical report. Copenhagen, Denmark: Copenhagen Center for Health Technology, 2018. Available from http://www.cachet.dk/research/ cumacf.

cachet | Copenhagen Center for Health Technology

#1 – User Adoption

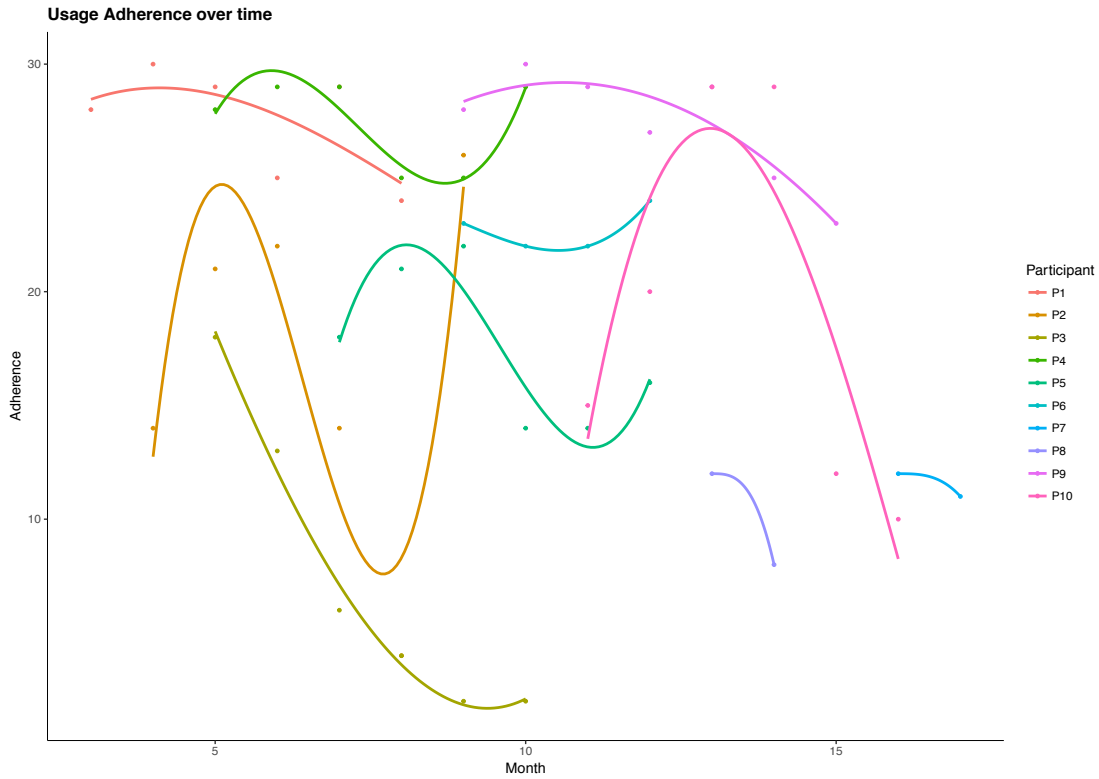
$$adoption = \frac{usage}{length - downtime}$$

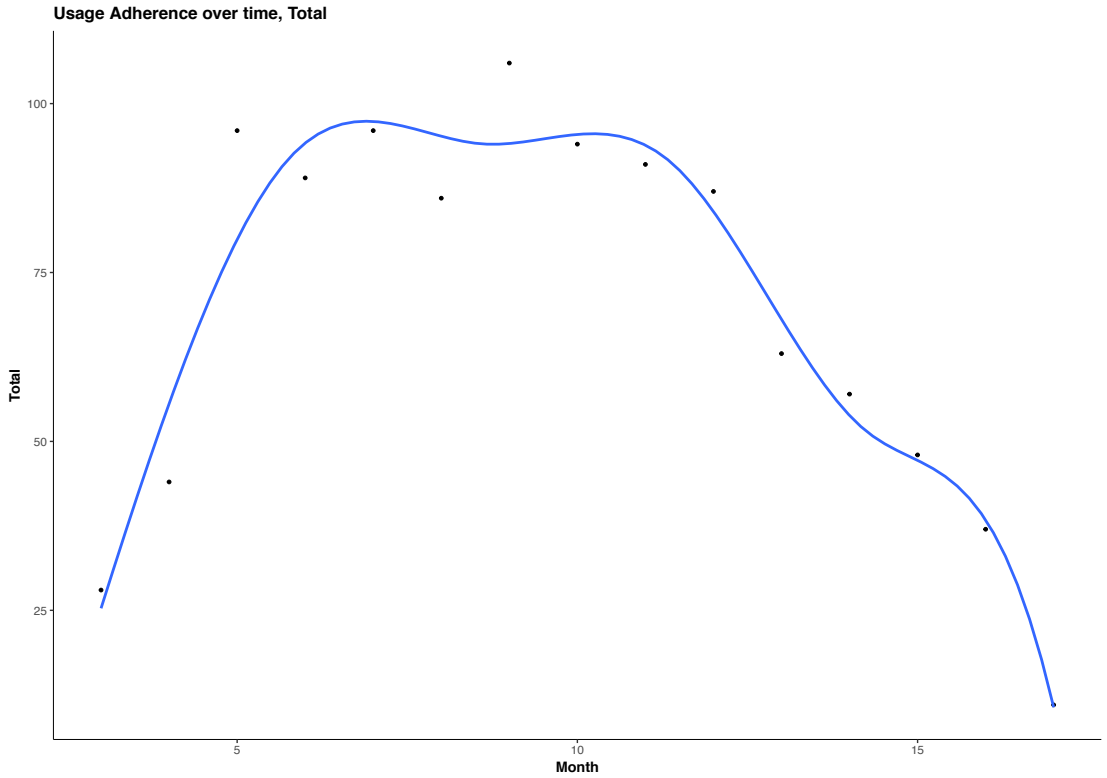
Example

Table 4.1: Example of usage adoption data collected. In this example, all reported number are days of a study..

participant	instr.	lenght	downtime	usage	adoption
P1	183	170	3	165	99%
P2	183	120	2	101	86%
P3	183	73	2	45	63%
P4	183	173	1	156	91%
P5	183	108	1	105	98%
P6	122	93	1	91	99%
P7	61	45	2	23	53%
P8	30	23	0	20	87%
P9	183	194	1	191	99%
P10	183	118	3	115	100%
total		1.117	16	1.012	**92%**
avg.					**87%**

Example





cachet | Copenhagen Center for Health Technology

#2 – Perceived Usefulness and Usability

- CUMACF builts on
  - the Unified Theory of Acceptance and Use of Technology (UTAUT) methodology [Ven+03]
  - the Post-Study System Usability Questionnaire (PSSUQ) scale [Lew92]
  - the Behavior Change Wheel (BCW) methodology [MSW11].

- By following the UTAUT methodology (which builds on the Technology Acceptance Model (TAM) methodology), CUMACF is designed to
  - assess the user's intention for **future acceptance** of the technology.

- As such, CUMACF does not assess usability of past usage
  - which is the case in other usability methods like PSSUQ and SUS

UTAUT

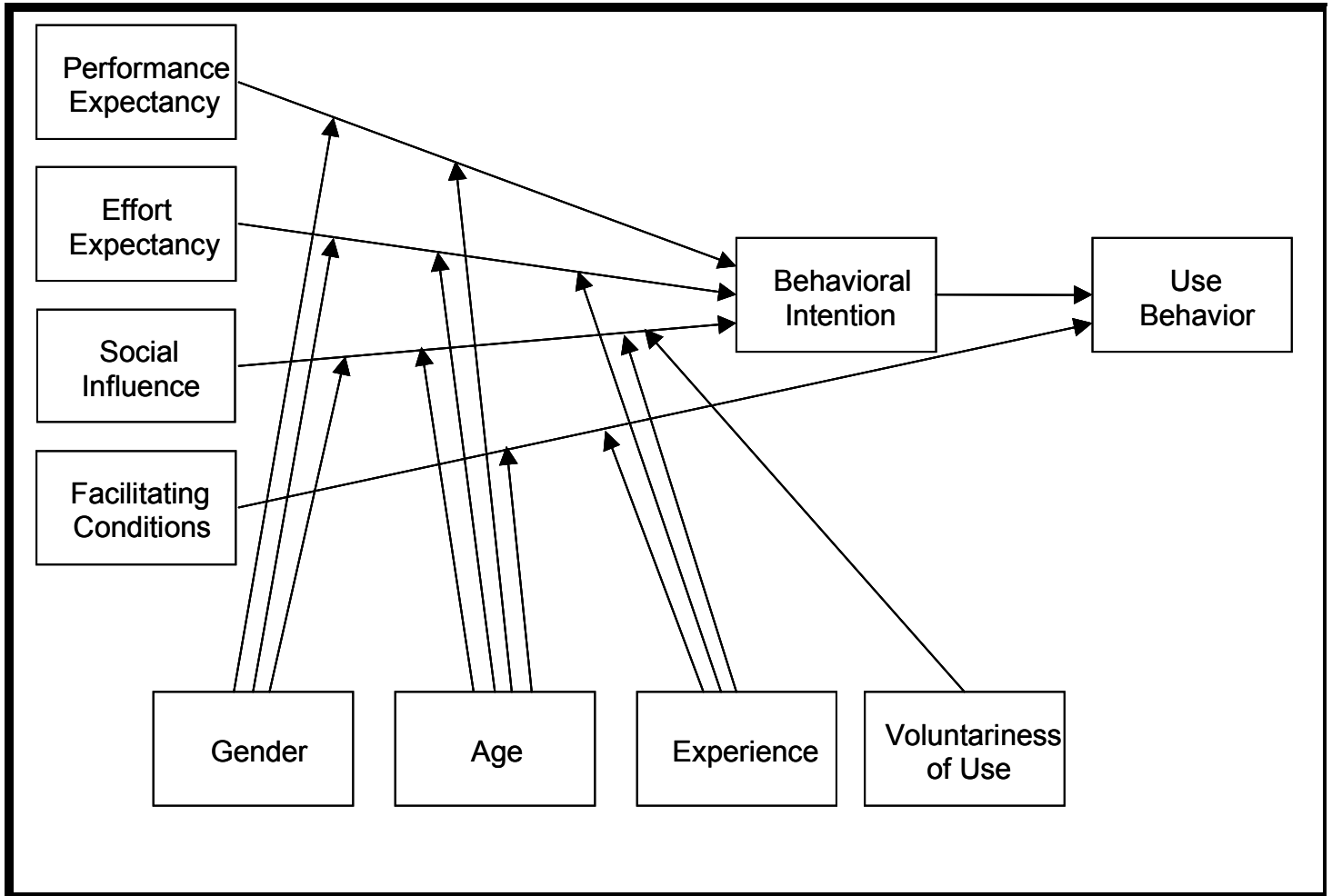


Figure 3. Research Model

cachet | Copenhagen Center for Health Technology

CUMACF

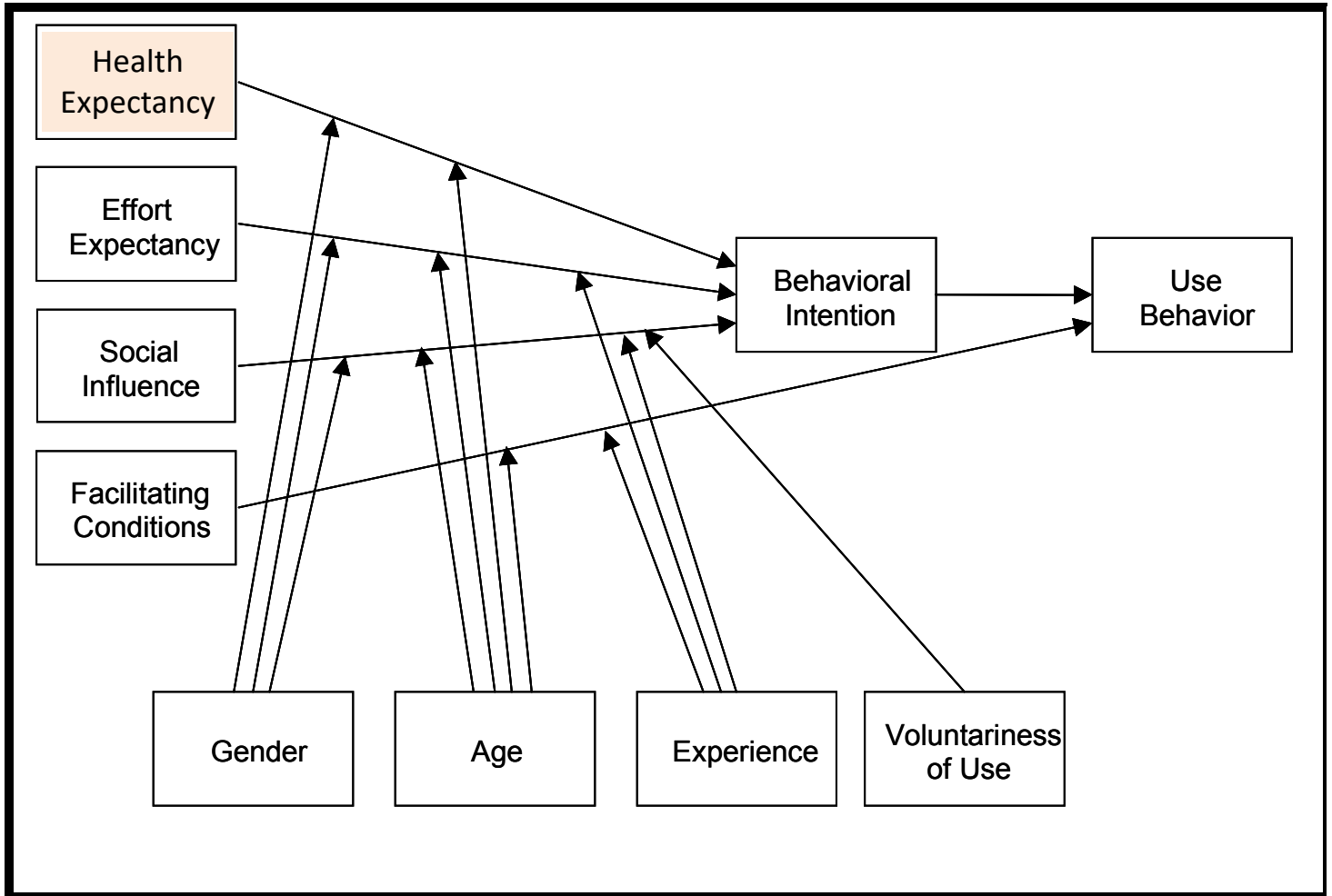


Figure 3. Research Model

cachet | Copenhagen Center for Health Technology

Health Expectancy (HE)

Table 3.1: Health Expectancy (HE) Questions..

ID	Target	Statement	Who	Source
HE1	Usefulness	Overall, I would find the system useful for [handling | improving] my [condition]	P	UTAUT
HE2	Adherence	I would use [system name] as often as instructed [(i.e. on a [daily | weekly | monthly | ...] basis)]	A	BCW
HE3	Behavior	Using [system name] would help me [reduce | increase] my [weight | physical activity | medicine adherence | ...]	P	BCW
HE4	Health	Using [system name] would help me reach my health goals of [reducing my blood pressure | managing my blood sugar and diabetes | reduce depressive symptoms | ...]	P	
HE5	Efficiency	Using [system name] would enable me to achieve my health goals more quickly and more efficiently	P	UTAUT
HE6	Productivity	Using [system name] would increases my productivity in terms of [consulting with more patients | handling more patient cases | ...].	C	UTAUT
HE7	Quality	Using [system name] would increases the quality of [treatment | care | communication b/w me and my doctor | ...]	A	UTAUT
HE8	Safety	Using [system name] would reduce [adverse events such as] [medication errors | readmission to hospital | mis-communication with my doctor | ...]	A	

cachet | Copenhagen Center for Health Technology

Effort Expectancy (EE)

Table 3.2: Effort Expectancy (EE) Questions..

ID	Target	Statement	Who	Source
EE1	Usability	Overall, I would be satisfied with how easy it is to use [system name]	A	PSSUQ
EE2	Understan-dability	My interaction with [system name] would be clear and understandable.	A	UTAUT
EE3	Learning	It would be easy for me to learn to use [system name]	A	UTAUT
EE4	Easy	I would find [system name] easy to use	A	UTAUT
EE5	Skillful	I would be skillful at using [system name]	A	UTAUT
EE6	Information Quality	The information (such as [error messages | on-line help | messages | guidelines | tutorials | ...]) provided with [system name] are clear and useful	A	PSSUQ
EE7	Interface Quality	The interface would be effective in helping me complete the [tasks | self-assessment | ...]	A	PSSUQ
EE8	Pleasure	[system name] would be pleasant to use.	A	PSSUQ
EE9	Features	[system name] would have all the [features | functionality | capabilities] that I expect it to have.	A	PSSUQ

Social Influence (SI)

Table 3.3: Social Influence (SI) Questions..

ID	Target	Statement	Who	Source
SI1	Health professionals	My [doctor | psychiatrist | psychologist | nurse | ...] think that I should use [system name].	P	UTAUT
SI2	Relatives	My family [spouse | children | parents | ...] think that I should use [system name].	P	UTAUT
SI3	Friends & Peers	My peer(s) ([friends | colleagues | care community |...]) think that I should use [system name].	P	UTAUT
SI4	Society	As a [Danish] citizen, I am expected to use [system name].	P	UTAUT

Facilitating Conditions (FC)

Table 3.4: Facilitating Conditions (FC) Questions..

ID	Target	Statement	Who	Source
FC1	Resources	I would have the resources necessary to use [system name] (such as [laptop | smartphone | ...]).	A	UTAUT
FC2	Knowledge	I would have the knowledge necessary to use [system name].	A	UTAUT
FC3	Support	A specific person (or group) would be available for [assistance | support] with system [difficulties | questions | technical issues].	A	UTAUT

Behavioural Intention (BI)

Table 3.5: Behavioural Intention (BI) Questions..

ID	Target	Statement	Who	Source
BI1	Intent	I intend to use [system name] in the next [2 | 6 | 12] months.	A	UTAUT
BI2	Predict	I predict I would use [system name] in the next [2 | 6 | 12] months.	A	UTAUT
BI3	Plan	I plan to use [system name] in the next [2 | 6 | 12] months.	A	UTAUT

Example

Table 4.2: Example of survey data from the CUMACF perceived usefulness and usability questionnaire. The center figures are the number of respondents in each category, and total and average scores are on the right..

#	Question	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Scores Total	Scores Avg.
HE1	Usefulness	20	0	0	0	20	120	24.0
HE2	Adoption	0	0	40	0	0	120	24.0
HE3	Behavior	10	10	0	10	10	120	24.0
HE4	Health	12	2	4	6	23	167	33.4
HE5	Efficiency	2	14	32	21	3	225	45,0
HE6	Productivity	32	2	3	12	2	103	20.6
HE7	Quality	10	2	4	1	23	145	29.0
HE8	Safety	4	14	2	33	3	185	37.0
EE1	Usability	12	2	5	2	3	54	10.8
EE2	Understandable	10	2	4	6	23	165	33.0
EE3	Learning	4	2	23	12	11	180	36.0
EE4	Easy	28	11	5	4	3	96	19.2
EE5	Skillful	18	2	4	6	11	113	22.6
EE6	Information	4	14	32	15	3	203	40.6
EE7	Interface	5	21	5	4	3	92	18.6
EE8	Pleasure	12	14	11	3	4	105	21.0
EE9	Features	4	4	3	44	12	257	51.4

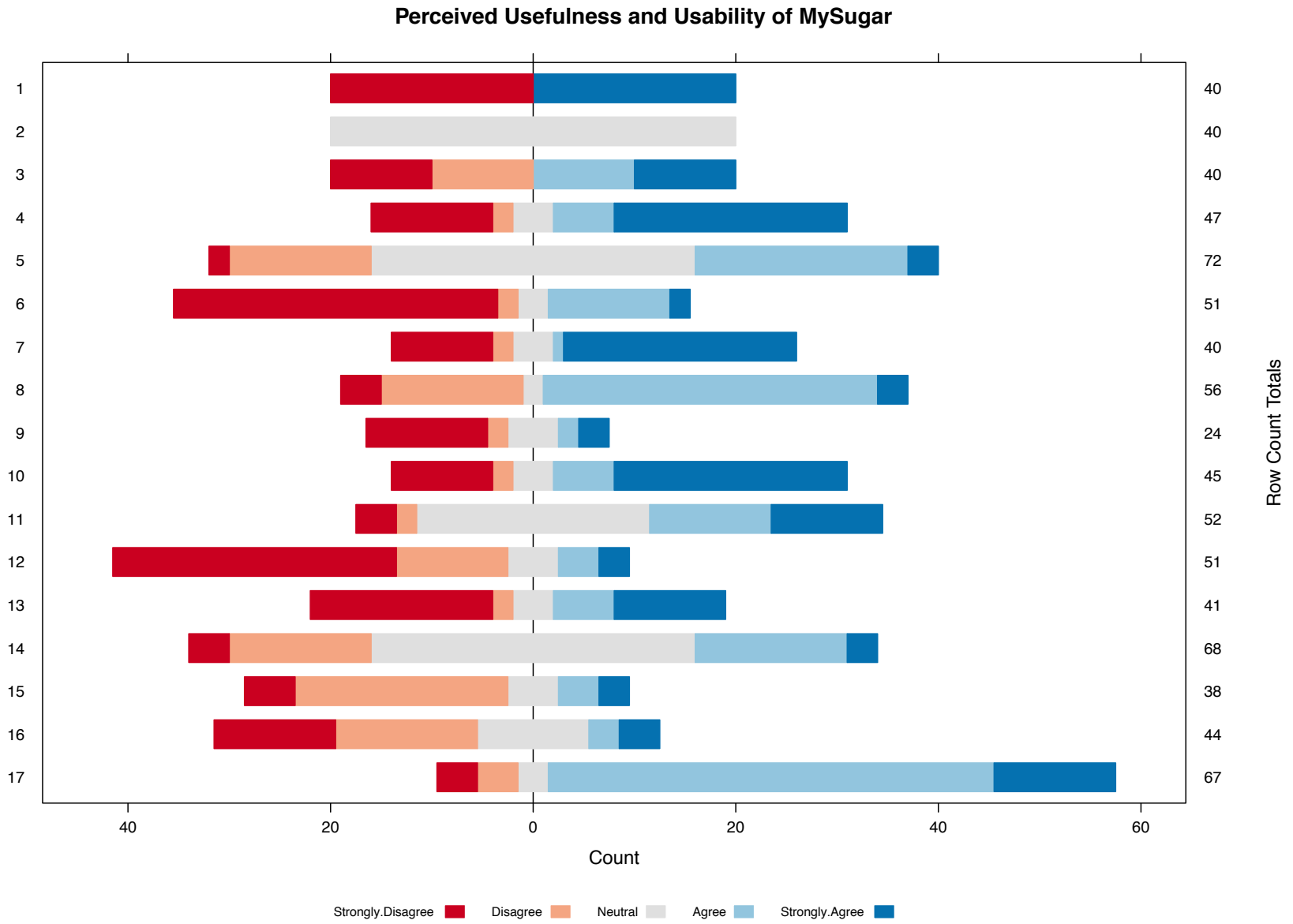


Figure 4.2: Diverging stacked bar chart of the data in Table 4.2.

#3 – Health Efficacy

- Efficacy – "can it work?"
  - is the extent to which an intervention does more good than harm under **ideal** circumstances
- Effectiveness – "does it work in practice?"
  - whether an intervention does more good than harm when provided under **usual** circumstances of healthcare practice
- Efficiency – "is it worth it?"
  - the effect of an intervention in relation to the **resources** it consumes

'Clinical Proof-of-Concept'

"The construction of working prototypes of the necessary functionality and infrastructure in sufficient quality to investigate evidence for improving health in daily use for a suitable period of time; a limited but relevant set of people serving as subjects." [p. 184]

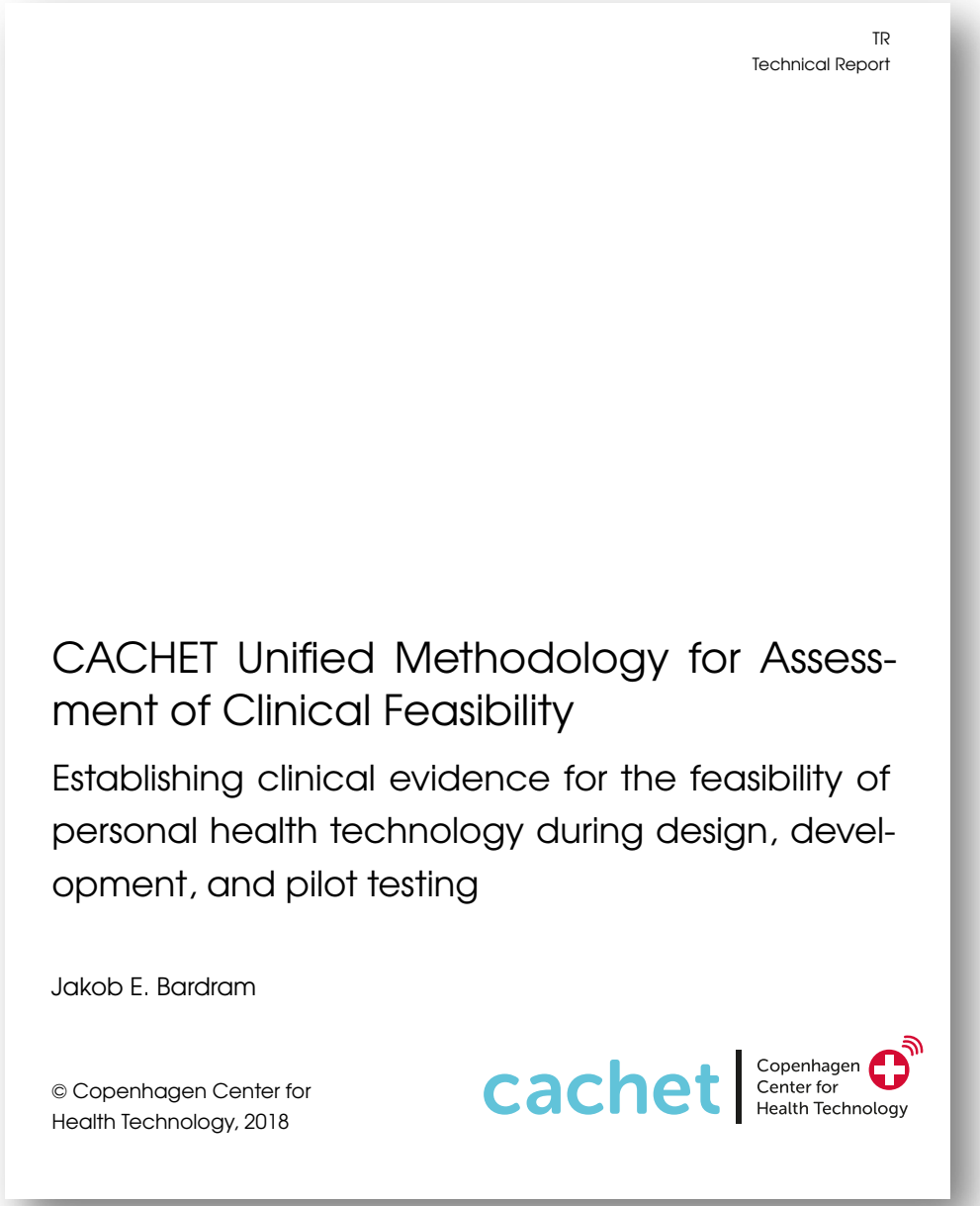
Recommendations…

- **N** = 20
- 1 mon < T < 6 mon
- Recruitment
  - patient (i.e. diagnosed)
  - "early adopters"
- Use compensation
- Allow for adaptation of protocol
  - especially on non-functional tech parameters
- Apply qualitative methods
  - in order to understand the "why", "how", "when", "what" of use

Outcome Measurement

Table 3.6: Taxonomy for measuring health outcome in a clinical pilot study.

	Health Professional	**Patient**	**Automatic**
Measurement (device)	*Clinical measurement* • in clinic • by clinician • approved medical device • documented in medical record	*Self-measurement* • at home by patient • limited training • non-approved medical device • documented by patient	*Automatic measurement* • continuously • mounting and maintenance by patient • any devices • automatic logging
Assessment (human)	*Clinical assessment* • in clinic • trained • verified clinical assessment methods • documented in medical record	*Self-assessment* • at home by patient • limited training • patient reported outcome (PRO) • documented by patient	*Automatic assessment* • continuously • calibration & training • verified against clinical assessment methods • automatic logging



#1 – User Adoption

#2 – Perceived Usefulness & Usability

#3 – Health Efficacy

Jakob E. Bardram. *CACHET Unified Methodology for Assessment of Clinical Feasibility*. Technical report. Copenhagen, Denmark: Copenhagen Center for Health Technology, 2018. Available from http://www.cachet.dk/research/ cumacf.

cachet | Copenhagen Center for Health Technology

cachet | Copenhagen Center for Health Technology

HOME NEWS RESEARCH INNOVATION EVENTS ABOUT

CACHET › Research › Methodology

- Research Projects
- PhD Projects
- Past PhD Projects
- Methodology
- Studies
- Publications

CACHET Unified Methodology for Assessment of Clinical Feasibility

This technical report describes the *CACHET Unified Methodology for Assessment of Clinical Feasibility* (CUMACF). The purpose of this methodology is to provide a standardized way across CACHET projects to assess `clinical feasibility' of the technologies that are being designed and tested.

From a health-oriented perspective, a carefully designed Randomised Clinical Trials (RCT) which minimises the possibility of bias has become accepted as the `gold standard' for determining the effectiveness of pharmacological agents, and this approach has been transferred to evaluating non-pharmacological interventions, including health technology. However, the traditional RCT approach has a set of limitations for evaluating health technology, including the fact that the RCT does not permit iterative improvements to the design and that the technology may be outdated by the time the trial is complete.

http://www.cachet.dk/research/cumacf

cachet | Copenhagen Center for Health Technology

cachet

Copenhagen Center for Health Technology

Technical University of Denmark

The Capital Region of Denmark

CITY OF COPENHAGEN

UNIVERSITY OF COPENHAGEN