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# Virkemekanismer for e-helse intervensjoner

og isbjørn på drivis

## Håvar Brendryen

"Yngre fremragende forsker"





## Fremragende?

- PhD med Happy Ending i Addiction
  - Brendryen H, Kraft P (2008). Happy Ending: a randomized controlled trial of a digital multi-media smoking cessation intervention. *Addiction*, 103(3):478-84.
- NFR-finansiert 4 årig prosjekt
  - Testing the efficacy of a lapse management system in an online smoking cessation intervention

## E-helse intervensjoner

- Teknologimediert terapi
  - Person til person terapi/rådgivning som medieres via IKT (sanntid/delay)
- Selvhjelp i sosiale medier
  - Selvhjelpsgrupper, diskusjonsforum, med eller uten moderator/helsearbeider

## Automatisert "selvhjelp"

- Kort-intervensjoner: kartlegging og tilbakemelding, en økt
- Intensive oppfølgingsintervensjoner
  - Passive eller proaktive (epost, SMS el. app m/varsel)
  - Interaktive, persona, arbeidsallianse
- Sensorteknologi
  - Skrittellere, pust & pulsklokke, hudkonduktans, akselerometer, GPS, subkutan sensor etc. som kan kobles til andre enheter og et atferdsendringsprogram
- "Fornuftige dataspill"

## Egner seg aller best for:

- Store grupper med relativt homogene behov
  - Folkehelseproblemene
- Forebygging, tidlig-intervensjon, lavterskel eller som første trinn i en "stepped care" tilnærming
- Prekliniske case og den "enkleste halvdelen" av case
- De med noe motivasjon for endring

## Studier av E-helse intervensjoner

- Kosthold & mosjon
- Røykeslutt
- Alkohol
- Depresjon og angst → Prevalens: 1/10
- Håndtere kronisk sykdom
- Andre rusmidler og gambling
  - mest på cannabis nesten ingenting på opiater, meth etc

2/5 dødsfall

Mokdad et al. (2004) Actual causes of death in the United States, 2000. JAMA, 291:1238-45.

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## Hvorfor eHelse intervensjoner?

## Hvorfor eHelse intervensjoner?

# LAV MARGINAL-KOSTNAD

## **Andre fordeler**

- Lav stigma, høy autonomi
- Datamaskiner husker alt og gjør det du ber dem om ALLTID
  - "treatment fidelity"
- Mister ALDRI tålmodigheten
- Tilgjengelig døgnet og året rundt også i grisgrendte strøk

## Happy Ending: a randomized controlled trial of a digital multi-media smoking cessation intervention

#### Håvar Brendryen & Pål Kraft

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#### **ABSTRACT**

Aims To assess the long-term efficacy of a fully automated digital multi-media smoking cessation intervention. Design Two-arm randomized control trial (RCT). Setting World Wide Web (WWW) study based in Norway. Participants Subjects (n = 396) were recruited via internet advertisements and assigned randomly to conditions. Inclusion criteria were willingness to quit smoking and being aged 18 years or older. Intervention The treatment group received the internet- and cell-phone-based Happy Ending intervention. The intervention programme lasted 54 weeks and consisted of more than 400 contacts by e-mail, web-pages, interactive voice response (IVR) and short message service (SMS) technology. The control group received a self-help booklet. Additionally, both groups were offered free nicotine replacement therapy (NRT). Measurements Abstinence was defined as 'not even a puff of smoke, for the last 7 days', and assessed by means of internet surveys or telephone interviews. The main outcome was repeated point abstinence at 1, 3, 6 and 12 months following cessation. Findings Participants in the treatment group reported clinically and statistically significantly higher repeated point abstinence rates than control participants [22.3% versus 13.1%; odds ratio (OR) = 1.91, 95% confidence interval (CI): 1.12–3.26, P = 0.02; intent-to-treat). Improved adherence to NRT and a higher level of post-cessation self-efficacy were observed in the treatment group compared with the control group. Conclusions As the first RCT documenting the long-term treatment effects of such an intervention, this study adds to the promise of digital media in supporting behaviour change.

# Vi ønsker å hjelpe flere folk ut av avhengighet - HVA virker?

- Cahill et al. (2011). Nicotine receptor partial agonists for smoking cessation. (Cochrane review.)
  - + Cahills konklusjon: Varenicline funker!
- Whittaker et al. (2009). Mobile phone-based interventions for smoking cessation. (Cochrane rev.)
  - + Whittakers konklusjon: Intervensjoner basert på mobiltelefoner kan funke.

## Men HVA OM?

- ★ Cahill et al. (2011). receptor partial agonists for smokiNicotine ng cessation. (Cochrane review.)
  - + Konklusjon: Varenicline funker!
- Whittaker et al. (2009). Mobile phone-based interventions for smoking cessation. (Cochrane rev.)
  - + Konklusjon: Intervensjoner basert på mobiltelefoner kan fungere.
- Von Münchausen et al. (1897). Tablett-baserte intervensjoner for røykeslutt. (Imaginært review)
  - + Konklusjon: Tabletter virker ikke.

## Late og inkompetente forskere!

- Gidder ikke skrive tilstrekkelig detaljert metodeseksjon
- At vitenskap skal være etterrettelig og etterprøvbar har gått dem hus forbi
  - Ting tyder på at dette i særlig grad gjelder psykologer o.l.
    - Dere så jo det gjaldt de psykososiale tiltakene, ikke den medikamentelle behandlingen!

## Happy Ending: the multi-channel, digital media smoking cessation intervention

Happy Ending is a fully automated and digitally delivered smoking cessation intervention. Table 1 shows the potential contact points between Happy Ending and the client for the entire programme period. Note from Table 1 that until week 11 the intervention has multiple daily contact points and is highly intensive, but from week 11 onwards the intervention switches to a markedly lower intensity. Early in the morning, the user receives an e-mail with instructions to open the day's web page. Each day for 6 weeks, the client opens a web page that is unique to that particular programme day. By means of cell-phone, the user receives one pre-recorded audio message, and up to three text messages throughout each day. The audio message is received when the client logs on to the programme in the morning, by calling an interactive voice response (IVR) service. Each evening the client receives a proactive log-off call, which asks whether or not they have been smoking. If so, the client will receive the automatically launched relapse prevention therapy (i.e. listen to a pre-recorded audio message) which relates to the specific number of lapses the client has reported. See Table 1 for details on the number of contact points and their distribution over the programme period. If the user does not log on to the programme or answers the log-off call, they will receive a reminder call, and up to two

reminder text messages. The programme also includes a craving helpline. The helpline is IVR-based and is available 24 hours a day from day 15 (cessation day) throughout the programme. We stress that each contact point, including the reminders, the telephone calls and the helpline, was 100% automated on the intervention side.

Redaktør refuserte beskrivelsen av Happy Ending (3500 ord)

Refereene var opptatt av å få det nøyaktige antallet kontaktpunkter for hver type kommunikasjon (SMS, IVR, e-post etc.), ikke behandlingsrasjonalet.

Red. foreslo engelsk ord for ord oversettelse av alt innhold som appendix (hundrevis av sider)

### THE INTERNET: JUST ANOTHER SMOKING CESSATION TOOL?

To have a significant impact on the public's health, smoking cessation programs must elicit high rates of participation and long-term cessation. In the real world, combining high reach and effectiveness has proven difficult. As Hughes [1] elegantly points out, smokers are most likely to use the least effective cessation interventions and least likely to use the most effective interventions. What seems clear is that most smokers prefer to quit smoking on their own, possibly with minimal contact assistance that maintains self-determination and autonomy [2]. The internet may be well suited to providing a little help at the right time.

Brendryen and Kraft [3] use a well-designed randomized controlled trial to demonstrate the long-term effectiveness of an internet-based smoking cessation program. The incremental jump in cessation from the internet versus control condition is both statistically significant and large in magnitude. The results of this trial also build on results of other randomized trials of internet-based cessation programs [e.g. 4–6] that had shorter follow-up periods and/or lower response rates at follow-up.

Internet-based smoking cessation programs may represent more than just another tool in our tobacco control kit. With their ability to efficiently address the participation/efficacy conundrum, internet-based programs may represent a completely new class of cessation tool. In 2005, over 8.6 million US smokers reported using the internet for information about quitting smoking in the past year [7; for a similar result see 8]. This rate of internet use for smoking cessation compares favorably with the estimate of roughly 800 000 in the USA calling quitlines each year for cessation advice [9]. Internetbased smoking cessation programs offer other advantages as well, particularly their ability to scale to millions of smokers while preserving the original effectiveness (i.e. fidelity). Moreover, once an internet-based program has been built, the cost of reaching a million smokers is not much more than reaching 1000 smokers.

While smokers appear to be turning to the internet for help in quitting, it is not at all clear that most current programs on the internet are up to the task. Go to a search engine such as Google and type in 'quit smoking'. Spend some time going through the prioritized sites. You'll likely agree that there is a reason most of these sites have never made the effort of being evaluated in a transparent, randomized controlled trial. Many sites consist of simple hortatory requiring the user to navigate through a labyrinth of html pages. Other sites are excessively busy and confusing, occasionally containing inaccurate or even harmful information. Still other sites offer little more than one-size-fits-all digital pamphlets.

The accumulated evidence, capstoned by the Brendryen and Kraft [3] results, suggests that effective, completely automated smoking cessation programs can be developed for the public. It's time to move effective internet-based programs into the real world, displacing the untested online programs that have thrived from snake-oil promises. A responsible first step would be for a national government to offer a proven internet-based smoking cessation program, at no cost, to all of their citizens.

The next generation of research in this area should proceed in two directions: (i) opening the 'black box' of these interventions to better understand and improve their quality, and (ii) optimizing and packaging these interventions for real-world dissemination. It is noteworthy that in well-designed randomized trials, some internet-based cessation programs have proven efficacious [e.g. 3] while others, even those designed by true experts in the field, have not [e.g. 10]. This would suggest that unpacking and testing the potentially active components of the programs could uncover features that are particularly effective, and other features that are ineffective or even harmful; this would create generalizable guidelines for even more effective programs [11–12].

The particular design used in the Brendryen and Kraft [3] study fails to uncover the reasons for its success. Comparing the Happy Endings program to printed materials demonstrates that this black box program works better than an intervention that is usually shown to fail: this is important news to the tobacco control community. It's now time, however, to understanding why and how these programs work and to get them into the real world. Perhaps then smokers might become more likely to use effective cessation interventions.

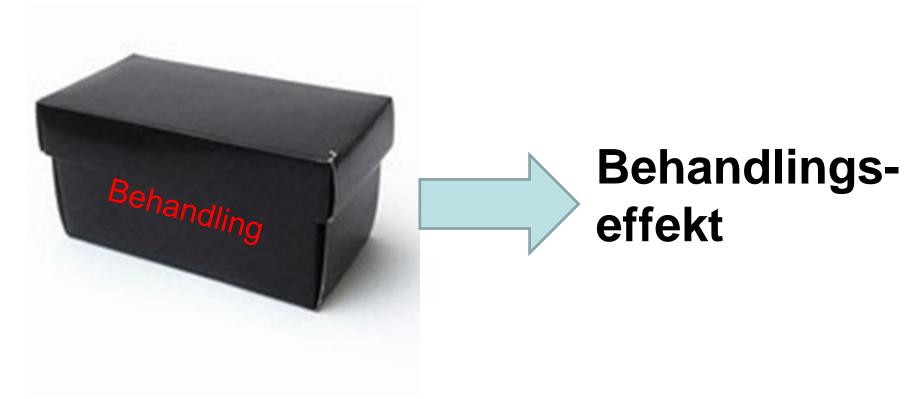
#### DISCLOSURE

Dr Strecher is founder, shareholder, and Chairman of HealthMedia, Inc., a company that produces internetbased smoking cessation programs and other health promotion, disease prevention, and disease management tools largely for health care organizations, employers, and pharmaceutical companies. Dr. Strecher has no association, financial or otherwise, with the Happy Endings Program developed by Brendryen and Kraft. The accumulated evidence, capstoned by the Brendryen and Kraft [3] results, suggests that effective, completely automated smoking cessation programs can be developed for the public. It's time to move effective internet-based programs into the real world, displacing the untested online programs that have thrived from snake-oil promises. A responsible first step would be for a national government to offer a proven internet-based smoking cessation program, at no cost, to all of their citizens.

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## The black box problem



Hvordan kan vi replikere, lære av eller forbedre denne behandlingen?

## The black box problem

- Multi-komponent programmer testes som én helhetlig pakke
- Programmet er ofte dårlig beskrevet
- Kun en håndfull eksperimentelle studier på komponentnivå
- Vi vet ikke hva vi gjør!

## **Botsøvelse**

Strechers kommentar i Addiction ga støtet til en artikkel som grundig beskriver det som på forhånd ble puttet inn i den svarte boksen (10.000 ord vs 3200 i addiction) OG har preget alt jeg senere har gjort



ARTICLE AVAILABLE ONLINE
Journal of Smoking Cessation

Looking Inside the Black Box:
Using Intervention Mapping to Describe
the Development of the Automated Smoking
Cessation Intervention 'Happy Ending'

Håvar Brendryen,¹ Pål Kraft,¹ and Herman Schaalma²

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## Partiell tilgivelse fra Riley et al., 2011

"In a separate report, Brendryen and colleagues [31] provided a detailed description of the intervention mapping process for the development of the Happy Ending intervention ... This report provides a well-devised framework for the application of theory to a mobile health behavior intervention."

"Among these studies extensive thoughtful and examples of using theory to mobile guide intervention development (e.g., [31, 40]). In contrast, most of the mobile interventions studied treatment adherence and disease management areas did not report a theoretical basis for intervention development"

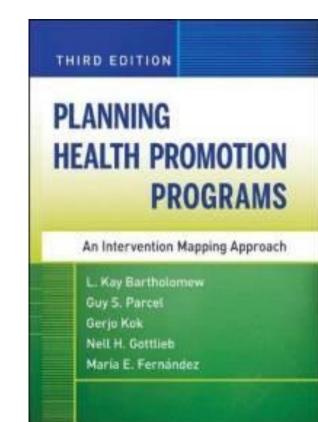
#### Sitater tatt fra:

Riley WT, Rivera DE, Atienza, AA, Nilsen, W, Allison, SM, Mermelstein R (2011). Health behavior models in the age of mobile interventions: are our theories up to the task? *Translational Behavioral Medicine*, *1*(1), 53-71.

http://www.springerlink.com/content/j963583533g56088/

## **Intervention Mapping**

- En praktisk håndbok som trinn for trinn tar deg gjennom prosessen med å planlegge, lage og implementere en psykososial intervensjon
- Rasjonalet for behandlingen
- http://www.interventionmapping.com/



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Brendryen H, Kraft P, Schaalma H (2010)

Looking Inside the Black Box: Using Intervention Mapping to Describe the Development of the Automated Smoking Cessation Intervention Happy Ending.

Journal of Smoking Cessation, 5(1), 29-56.

Brendryen H, Johansen AB, Nesvåg S, Kok G, Duckert F (2013)

Constructing a Theory- and Evidence-Based Treatment Rationale for Complex eHealth Interventions: Development of an Online Alcohol Intervention Using an Intervention Mapping Approach.

JMIR Research Protocols, 2(1):e6.

Drozd F, Haga SM, <u>Brendryen H</u>, Slinning K (2015)

An Internet-Based Intervention (Mamma Mia) for Postpartum Depression: Mapping the Development from Theory to Practice.

JMIR Research Protocols, 4(4)

Danaher BG, Brendryen H, Seeley JR, Tyler MS, Woolley T (2015)

From black box to toolbox: Outlining device functionality, engagement activities, and the pervasive information architecture of mHealth interventions.

Internet Interventions, 2(1), s 91- 101

Holter MTS, Johansen AB, Brendryen H (2016)

How a Fully Automated eHealth Program Simulates Three Therapeutic Processes: A Case Study.

Journal of Medical Internet Research, 18(6), s e176.

## Bakgrunn og premisser

- Atferd → folkehelse
  - Tobakk, alkohol, fysisk aktivitet og kosthold
- Endring av atferd er utfordrende for de fleste
  - Tenk nyttårsforsetter o.l.
- Det viktigste knapphetsgodet kan være selvregulering, ikke motivasjon
  - Majoriteten av røykere har prøvd å slutte og mange ønsker å slutte
- Læring (endring) innebærer å feile
- Hvordan feil håndteres kan være forskjellen på suksess og fiasko

## **Glipp**

- De fleste begynner å røyke igjen
- Episodisk (på/av)
- Et kritisk tidsvindu for intervensjon etter en glipp
- Subjektiv tolkning av å røyke igjen:
  - glipp eller sprekk?

## Tilbakefallsforebygging/glipphåndtering

- Marlatt sin modell for tilbakefallsforebygging
  - AVE: skyld, skam, skuffelse, selvbebreidelse
  - Årsaksattribusjon: eksterne, forbigående, spesifikke og kontrollerbare faktorer
- Ansvarliggjøring
  - Ingen unskyldning, det er nå avgjørelsen tas.
- Kan gjøres via internett og mobiltelefon
  - Unik erfaring fra to tidligere prosjekter
  - Daglig oppfølging og inngripen ved glipp

## Stipendiat: Marianne T.S. Holter

- Skrevet alt innhold i programmet
  - MI, røyketelfonen
- Publisert artikkel om behandlingsrasjonalet
- Kvalitative intervjuer med sluttbrukere
  - Formativ evaluering
  - Relasjonen til programmet
    - Ambivalens/skam over opplevelse av relasjon

## **Status**

- Røykesluttprogrammet "Endre" er ferdig.
  - Ikke akkurat Mongstad, men ...
- RCT starter etter påske
  - teste effekten av glipphåndteringsregimet
- Kvalitative intervjuer avsluttes vår 2017

## Determinants

Performance Objectives	Awareness & knowledge	Attitudes and cognitions	Norms	Planning	Self-efficacy	Skills and behavior
3a. Avoiding lapses by coping adaptively with the antecedents of smoking	Awareness of own vulnerability and the antecedents of smoking	Positive attitude towards using tools and therapy to change smoking habits	Feel personally responsible for adaptive coping	Make implementation intentions about activating tools and strategies to handle craving.	Coping self- efficacy	Implement selected coping plans during craving episodes Emotion- regulation skills
3b. Avoiding relapses by resuming the change attempt after a lapse	Know the psychological consequences of having a lapse and distinguish between a lapse and a relapse	Attribute failures to situational factor and achievements to own self	Starting to smoke again after a lapse is a deliberate choice not something that became inevitable after the lapse	Make an action plan, immediately after a lapse, to continue the quit attempt	Recovery self- efficacy Focusing on what's achieved rather than failure	Report smoking truthfully to the program

Note. The left column contains the performance objectives (in red), while the determinants are entered across the top of the matrix (in blue). The intersecting cells contains either learning objectives or change objectives (in green), describing what the participants in the intervention program need to learn or do (related to the determinant) to accomplish the performance objective.

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Personal Determinan t	Theoretical Method	Practical Strategy: What should be done?	Considerations for Use: How should it be done?		
Attitudes and cognitions	Cognitive restructuring (Cog. Beh. Therapy)	Identify and change counter productive thoughts. Provide list of typical such thoughts related to quitting smoking	Changing cognitions about causes and consequences of behavior (i.e., craving, the fear of failing etc.)		
	Operant conditioning Inform clients about the short term positive consequences of smoking cessation		Important to be aware of the short term positive consequences of quitting, because they represent positive reinforcement of the new behavior. Timing is important, and optimal timing will wary with the specific information.		
	Self-reward Encourage self-reward		The plan should include a concrete reward, a clear criterion for acquiring the reward, and it should be formed in advance.		
	Reattribution (Attribution theory)	Teach clients to explain setbacks and successes in terms of adaptive attributions	Requires unstable and external attributions for failure, and stable and internal attributions for mastery. Timing: optimistic attribution pattern should be primed early, and reinforced after lapse (just-in-time).		