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Behavioural Medicine for Global Health: Challenges and Opportunities

William Riley, Ph.D.
Associate Director for Behavioral and Social Sciences Research
Director, Office of Behavioral and Social Sciences Research
National Institutes of Health

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Influence of Behavioral Clinical Trials

Nearly 100K Behavior RCTs

Broad Influence

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EA

Interventions

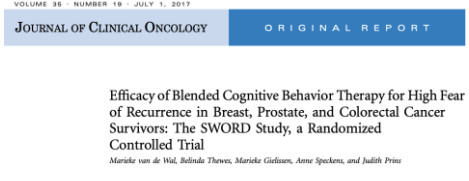
Effect of personalized nutrition on health-related behaviour change: evidence from the Food4Me European randomized controlled trial

Carlos Celis-Morales, [1,†] Katherine M Livingstone, [1,†]


Published in final edited form as:
Pain. 2016 January ; 157(1): 174–185. doi:10.1097/j.pain.0000000000000348.

Internet-delivered cognitive-behavioral treatment for adolescents with chronic pain and their parents: a randomized controlled multicenter trial

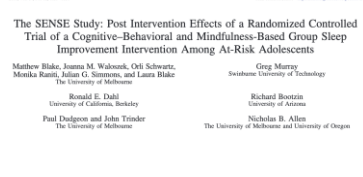
Tonya M. Palermo[a,b,*], Emily F. Law[a,b], Jessica Fales[c], Maggie H. Bromberg[b], Tricia Jessen-Fiddick[b], and Gabrielle Tai[b]


JOURNAL OF CLINICAL ONCOLOGY ORIGINAL REPORT

VOLUME 35 · NUMBER 19 · JULY 1, 2017

Efficacy of Blended Cognitive Behavior Therapy for High Fear of Recurrence in Breast, Prostate, and Colorectal Cancer Survivors: The SWORD Study, a Randomized Controlled Trial

Marieke van de Wal, Belinda Thewes, Marieke Gielissen, Anne Speckens, and Judith Prins


The SENSE Study: Post Intervention Effects of a Randomized Controlled Trial of a Cognitive–Behavioral and Mindfulness-Based Group Sleep Improvement Intervention Among At-Risk Adolescents

Matthew Blake, Joanna M. Waloszek, Orli Schwartz, Monika Raniti, Julian G. Simmons, and Laura Blake — The University of Melbourne

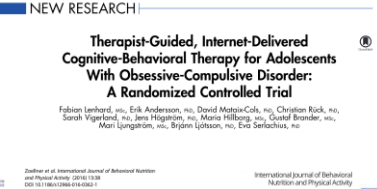
Greg Murray — Swinburne University of Technology

Ronald E. Dahl — University of California, Berkeley

Richard Bootzin — University of Arizona

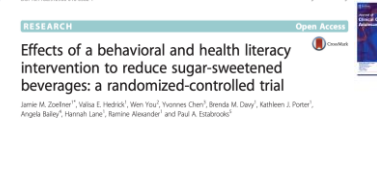
Paul Dudgeon and John Trinder — The University of Melbourne

Nicholas B. Allen — The University of Melbourne and University of Oregon


NEW RESEARCH

Therapist-Guided, Internet-Delivered Cognitive-Behavioral Therapy for Adolescents With Obsessive-Compulsive Disorder: A Randomized Controlled Trial

Fabian Lenhard, MSc, Erik Andersson, PhD, David Mataix-Cols, PhD, Christian Rück, PhD, Sarah Vigerland, PhD, Jens Högström, PhD, Maria Hillborg, MSc, Gustaf Brander, MSc, Mari Ljungström, MSc, Brjánn Ljótsson, PhD, Eva Serlachius, PhD


Zoellner et al. International Journal of Behavioral Nutrition and Physical Activity (2016) 13:38

International Journal of Behavioral Nutrition and Physical Activity

RESEARCH Open Access

Effects of a behavioral and health literacy intervention to reduce sugar-sweetened beverages: a randomized-controlled trial

Jamie M. Zoellner[1*], Valisa E. Hedrick[1], Wen You[1], Yvonnes Chen[1], Brenda M. Davy[1], Kathleen J. Porter[1], Angela Bailey[2], Hannah Lane[1], Ramine Alexander[1] and Paul A. Estabrooks[3]


BRIEF REPORT

A Randomized Controlled Trial of a Smartphone App for Posttraumatic Stress Disorder Symptoms

Eric Kuhn — Veterans Affairs Palo Alto Health Care System, Palo Alto, California, and Stanford University School of Medicine

Nitya Kanuri — Stanford University School of Medicine

Julia E. Hoffman and Donn W. Garvert — Veterans Affairs Palo Alto Health Care System, Palo Alto, California

Josef I. Ruzek — Veterans Affairs Palo Alto Health Care System, Palo Alto, California, and Stanford University School of Medicine

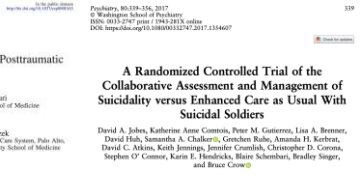
C. Barr Taylor — Stanford University School of Medicine and Palo Alto University


Journal of Clinical Child & Adolescent Psychology

Routledge

Acceptance and Commitment Therapy versus Cognitive Behavior Therapy for Children With Anxiety: Outcomes of a Randomized Controlled Trial

Karen M. Hancock, Jessica Swain, Cassandra J. Hainsworth, Angela L. Dixon, Siew Koo & Karen Munro


Psychiatry, 80:339–356, 2017

© Washington School of Psychiatry

ISSN: 0033-2747 print / 1943-281X online

DOI: https://doi.org/10.1080/00332747.2017.1354607

A Randomized Controlled Trial of the Collaborative Assessment and Management of Suicidality versus Enhanced Care as Usual With Suicidal Soldiers

David A. Jobes, Katherine Anne Comtois, Peter M. Gutierrez, Lisa A. Brenner, David Huh, Samantha A. Chalker, Gretchen Ruhe, Amanda H. Kerbrat, David C. Atkins, Keith Jennings, Jennifer Crumlish, Christopher D. Corona, Stephen O' Connor, Karin E. Hendricks, Blaire Schembari, Bradley Singer, and Bruce Crow


Psychotherapy and Psychosomatics

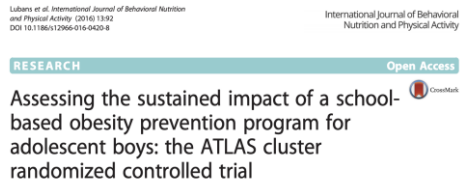
Regular Article

Psychother Psychosom 2016;85:159–170

DOI: 10.1159/000442824

Effectiveness of Trauma-Focused Cognitive Behavioral Therapy for Children and Adolescents: A Randomized Controlled Trial in Eight German Mental Health Clinics

Lutz Goldbeck[a] Rainer Muche[b] Cedric Sachser[a] Dunja Tutus[a] Rita Rosner[c]


Lubans et al. International Journal of Behavioral Nutrition and Physical Activity (2016) 13:92

DOI 10.1186/s12966-016-0420-8

International Journal of Behavioral Nutrition and Physical Activity

RESEARCH Open Access

Assessing the sustained impact of a school-based obesity prevention program for adolescent boys: the ATLAS cluster randomized controlled trial

David R. Lubans[1*], Jordan J. Smith[1], Ronald C. Plotnikoff[2], Kerry A. Dally[1], Anthony D. Okely[2], Jo Salmon[3] and Philip J. Morgan[1]


Journal of Consulting and Clinical Psychology 2016, Vol. 84, No. 5, 427–437

© 2016 American Psychological Association 0022-006X/16/$12.00 http://dx.doi.org/10.1037

Group CBT Versus MBSR for Social Anxiety Disorder: A Randomized Controlled Trial

Philippe R. Goldin — University of California, Davis

Amanda Morrison — Stanford University

Hooria Jazaieri — University of California, Berkeley

Faith Brozovich — Stanford University

Richard Heimberg — Temple University

James J. Gross — Stanford University

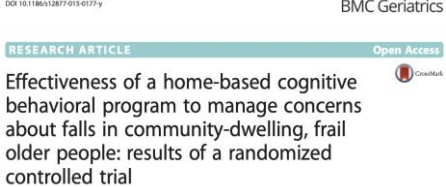

Support Care Cancer (2016) 24:2059–2066

DOI 10.1007/s00520-015-2996-y

ORIGINAL ARTICLE

Cognitive behavioral therapy for insomnia, but not armodafinil, improves fatigue in cancer survivors with insomnia: a randomized placebo-controlled trial

Charles E. Heckler[1] · Sheila N. Garland[2] · Anita R. Peoples[1] · Michael L. Perlis[3] · Michelle Shayne[1] · Gary R. Morrow[1] · Charles Kamen[2] · Jenine Hoefler[1] · Joseph A. Roscoe[1]


Domesteijn et al. BMC Geriatrics (2016) 16:2

DOI 10.1186/s12877-015-0177-y

BMC Geriatrics

RESEARCH ARTICLE Open Access

Effectiveness of a home-based cognitive behavioral program to manage concerns about falls in community-dwelling, frail older people: results of a randomized controlled trial

Tanja A. C. Domesteijn[1*], G. A. Rixt Zijlstra[1], Antonius W. Ambergen[2], Kim Delbaere[3], Johan W. S. Vlaeyen[4,5] and Gertrudis I. J. M. Kempen[1]

@ibtnetwork #ibtn2020

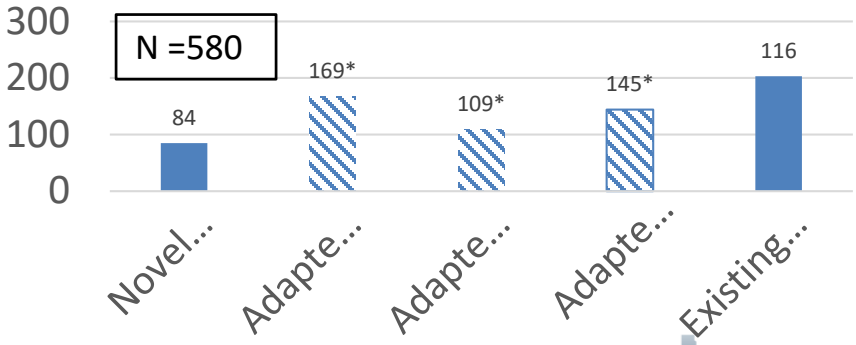
Challenges and Opportunities

- Basic to Applied Translation (T1)
- Methods
  - Comparators
  - Self-report of Unblinded Participants
  - Efficiency
- Post-Study Challenges
  - Publication Lags
  - Building a More Cumulative Science
  - Implementation
- Challenges and Opportunities with COVID-19

Improving T1 Translation

Preliminary Analyses of FY18 NIH Behavioral Intervention Grants

- 66% evaluating adaptations of existing interventions (different group, different delivery, different problem)
- 20% comparative effectiveness or D&I research
- 14% evaluating novel intervention components or packages



HHS Public Access
Author manuscript
Behav Res Ther. Author manuscript; available in PMC 2018 February 07.

Published in final edited form as:
Behav Res Ther. 2018 February ; 101: 3–11. doi:10.1016/j.brat.2017.07.002.

The NIH Science of Behavior Change Program: Transforming the science through a focus on mechanisms of change

Lisbeth Nielsen[a,*], Melissa Riddle[b], Jonathan W. King[a], the NIH Science of Behavior Change Implementation Team, Will M. Aklin[c], Wen Chen[d], David Clark[b], Elaine Collier[e], Susan Czajkowski[f], Layla Esposito[g], Rebecca Ferrer[f], Paige Green[f], Christine Hunter[h], Karen Kehl[i], Rosalind King[g], Lisa Onken[a], Janine M. Simmons[j], Luke Stoeckel[k], Catherine Stoney[l], Lois Tully[i], and Wendy Weber[d]

"The goal of the NIH Science of Behavior Change (SOBC) Common Fund Program is to provide the basis for an experimental medicine approach to behavior change that focuses on identifying and measuring the mechanisms that underlie behavioral patterns we are trying to change."

Selecting Appropriate Comparators

ELSEVIER

Check for updates

Journal of Clinical Epidemiology

Journal of Clinical Epidemiology 110 (2019) 74–81

REVIEW

The selection of comparators for randomized controlled trials of health-related behavioral interventions: recommendations of an NIH expert panel

Kenneth E. Freedland[a,*], Abby C. King[b], Walter T. Ambrosius[c], Evan Mayo-Wilson[d], David C. Mohr[e], Susan M. Czajkowski[f], Lehana Thabane[g], Linda M. Collins[h], George W. Rebok[d], Shaun P. Treweek[i], Thomas D. Cook[j], Jack D. Edinger[k], Catherine M. Stoney[l], Rebecca A. Campo[m], Deborah Young-Hyman[m], William T. Riley[m], for the National Institutes of Health Office of Behavioral and Social Sciences Research Expert Panel on Comparator Selection in Behavioral and Social Science Clinical Trials

- Positioning trial in an applicable research framework
- Defining the primary purpose
- Choosing the optimal comparator
  - Works at all?
  - Relative to clinically relevant alternatives?
  - How or why it works?
- Address barriers
- Address limitations
- Finalize choice

Unblinded Participants and Self-Report

Journal of Clinical Psychology, 69, 2012

The Discrepancy between Subjective and Objective Measures of Sleep in Older Adults Receiving CBT for Comorbid Insomnia

Hannah G. Lund,[1] Bruce D. Rybarczyk,[1] Paul B. Perrin,[1] David Leszczyszyn,[1] and Edward Stepanski[2]

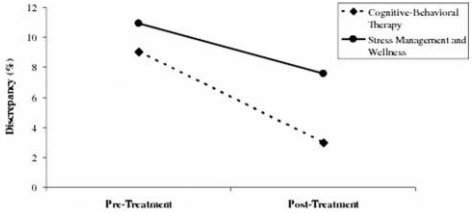


Figure 1. Discrepancy between Subjective and Objective Measures of Sleep Efficiency by Group at Pre- and Post-Treatment.

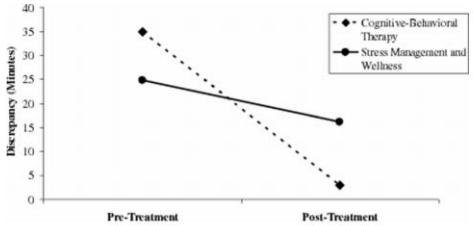


Figure 2. Discrepancy between Subjective and Objective Measures of Sleep Onset Latency by Group at Pre- and Post-Treatment.

Available online at www.sciencedirect.com
ScienceDirect
Journal of Sport and Health Science 4 (2015) 222–227
www.jshs.org.cn

Original article

Correlates of subjectively and objectively measured physical activity in young adolescents

Kelly Kavanaugh [a], Justin B. Moore [a,b,*], Leisha Johnson Hibbett [c], Andrew T. Kaczynski [b]

"Measuring MVPA via self-report versus accelerometry produces considerably different results in a sample of young adolescents."

- Fastidious about PI and RA blinding
- But unable to blind participants
- Larger effects from subjective vs. objective outcomes
- Outcomes need to extend beyond self-report

Rapid Research

R3 Research

- 7 yrs from grant submission to publication – much changes and findings may be dated by the time they are published.
- Need faster recruitment, designs, infrastructures and review
- Noted that in response to the SARS outbreak, the Canadian Institutes of Health Research developed and issued a funding announcement that resulted in submissions within 2 weeks, and that were approved for funding within 10 days of submission

Lessons from COVID-19 Research Response

- Rapid review and funding process
- Rapid development infrastructure
- Rapid trials infrastructure

Riley et al. Clinical and Translational Medicine 2013, 2:10
http://www.clintransmed.com/content/2/1/10

Clinical and Translational Medicine
a SpringerOpen Journal

PERSPECTIVE Open Access

Rapid, responsive, relevant (R3) research: a call for a rapid learning health research enterprise

William T Riley[1*], Russell E Glasgow[1], Lynn Etheredge[2] and Amy P Abernethy[3]

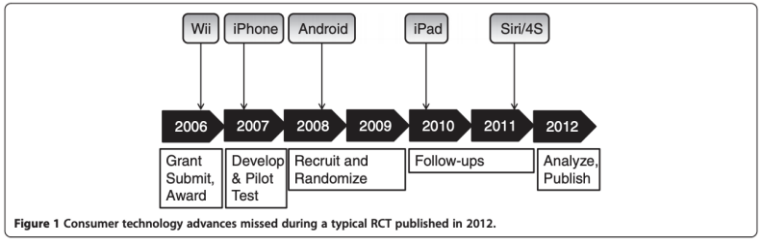


Figure 1 Consumer technology advances missed during a typical RCT published in 2012.

Publication Lags

- NIH trials funded in 1979 – 93% published within 9 yrs (Dickerson et al., 1993) [Interview of PIs]
- Phase I oncology trials – 67% published in 7.5 yrs (Camacho et al.,2005)
- IRB approved trials in Univ Hospital Bern – 52% published with 8 yrs (von Elm, et al, 2008)
- AMD ct.gov trials – 54% published within 2 yrs (Prenner et al., 2011)
- **Clinicaltrials.gov registered trials – 46% published within 30 mos.(Ross et al., 2012)**
- Large RCTs in ct.gov – 71% published within 2 yrs (Jones,et al., 2013)
- NHLBI Trials – 57% published within 30 mos. (Gordon, et al, 2013)

"Clinical Trials: What a Waste" Ioannidis, BMJ, 2015

NIH R01/U01, 2008-2014

- 655 had zero pubs at 60 mos
- 5% of BSSR grants
- 2% of non-BSSR grants

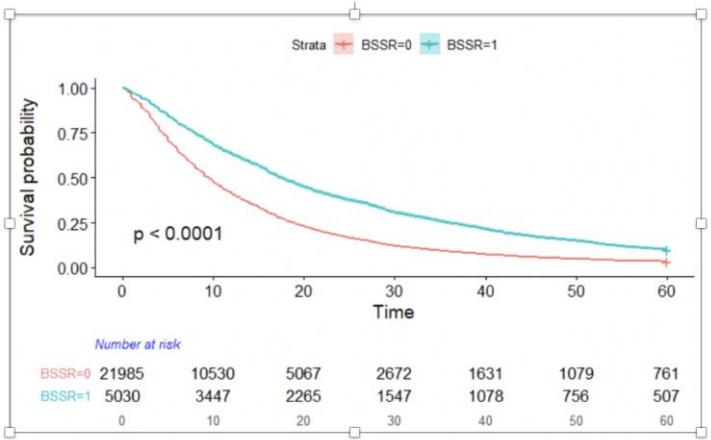
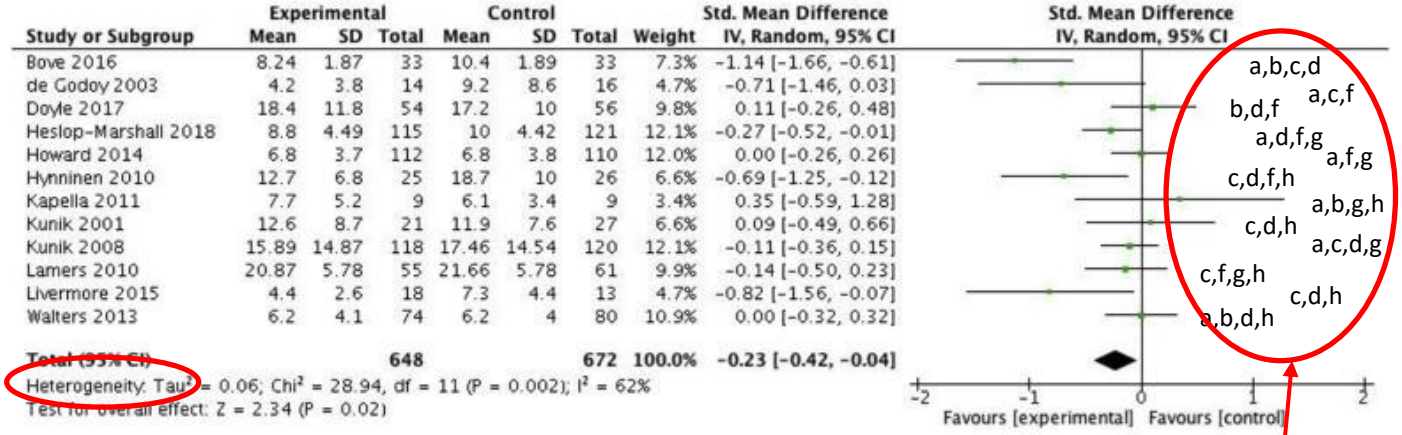


Figure 3 Survival curve for BSSR predictor. 0= non-BSSR, 1= BSSR

Building a More Cumulative Intervention Science

"despite numerous controlled trials of various interventions for a given problem, the field has little guidance on how to improve upon previously studied interventions, adapt them to specific populations, contexts, or delivery mechanisms, or streamline them to facilitate use in real-world settings with constrained resources.

Methodologies for Optimizing Behavioral Interventions: Intro to Special Section (Riley, Rivera, TBM, 2014.



Different components

Ma et al (2020) Effectiveness of cognitive behavioural therapy for chronic obstructive pulmonary disease patients: A systematic review and meta-analysis

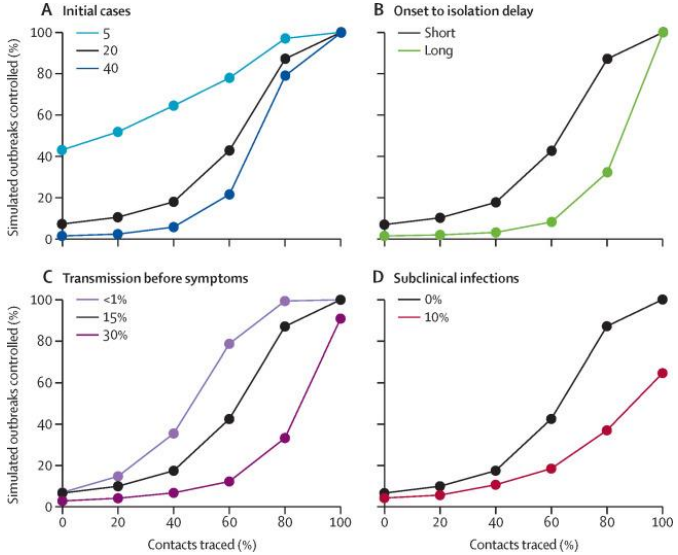
Implementation Challenges

- Well documented across all healthcare – "Valley of Death" (Meslin et al., 2013)
- Translation of social and behavioral interventions into practice present unique challenges:
  - Lack of a market-driven delivery system with accompanying regulatory structure
  - Inadequate health insurance reimbursement for effective interventions
  - When reimbursed - based on time, not quality or empirical basis
  - Settings in which behavioral interventions are delivered are much more diverse than medicine, and most have competing interests and strained resources
  - Behavioral interventions are complex and resource intensive, requiring considerable training and time to deliver with fidelity
- Strategies to Address Implementation Challenges
  - Interventions and Research Designs that Facilitate Adoption
  - Practice-based Research
  - Evaluating while Disseminating
  - Digital Technologies
  - Transition from Packages to Principles

Nature.com

COVID Social/Behavioral Research

- Most current mitigation efforts are social/behavioral interventions (risk communication, handwashing, paid sick leave, social distancing)
  - Based on varying levels of evidence from prior epidemics on adherence and transmission
  - Some with limited generalizability to an epidemic of this nature
  - Most with insufficient precision or quantification to better inform models
  - Some not implemented consistent with existing evidence
- Most with insufficient evidence to quantify "adverse events" such as rapid economic downturn, unemployment, social isolation, life disruption, limited healthcare access (cost-benefit analysis)
- The adverse effects of these mitigation strategies have downstream health effects:
  - Stress, mental health, and suicide
  - Substance abuse
  - Stress-related physical conditions
  - Domestic abuse, child abuse
  - But some positive outcomes as well (motor vehicle accidents, youth violence).

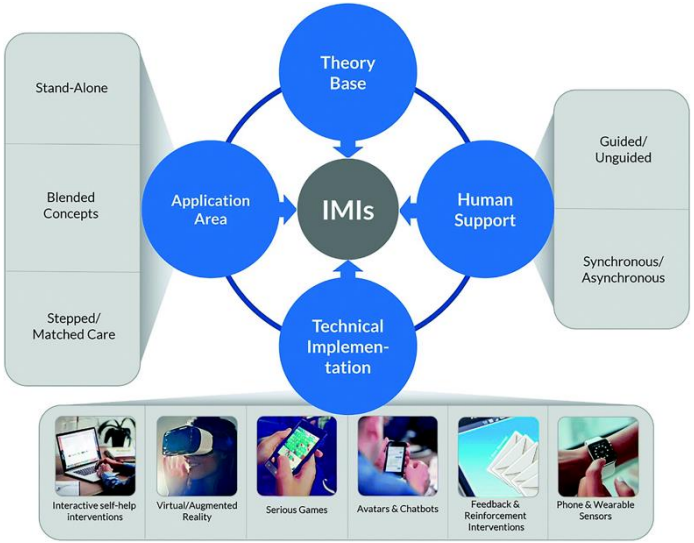


Achieving control of simulated outbreaks under different transmission scenarios

Hellewell et al., Feasibility of controlling COVID-19 outbreaks by isolation of cases and contacts; *Lancet Global Health*, 2020.

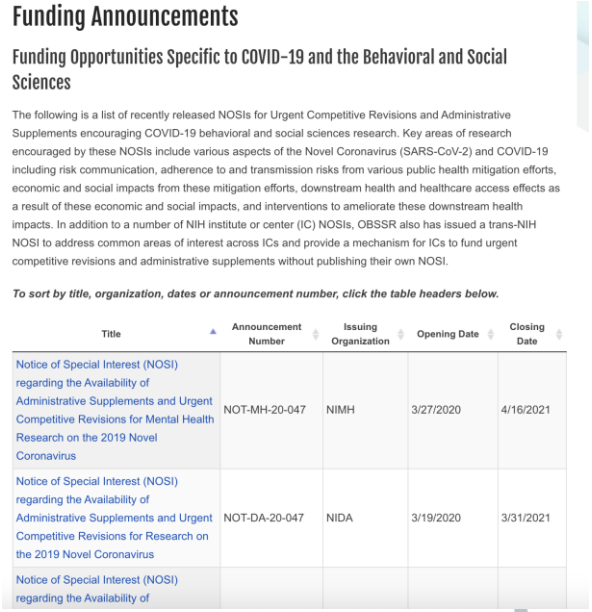
Interventions to Ameliorate Downstream Health Effects

- **Inadequate access to healthcare**
- **Exacerbation of Health Disparities**
- **Telehealth and Digital Interventions**



Ebert et al., Digital Interventions for Mental Disorders: Key Features, Efficacy, and Potential for Artificial Intelligence Applications *Frontiers in Psychiatry*, 2019.

COVID-19 Competitive and Administrative Supplements



Funding Announcements

Funding Opportunities Specific to COVID-19 and the Behavioral and Social Sciences

The following is a list of recently released NOSIs for Urgent Competitive Revisions and Administrative Supplements encouraging COVID-19 behavioral and social sciences research. Key areas of research encouraged by these NOSIs include various aspects of the Novel Coronavirus (SARS-CoV-2) and COVID-19 including risk communication, adherence to and transmission risks from various public health mitigation efforts, economic and social impacts from these mitigation efforts, downstream health and healthcare access effects as a result of these economic and social impacts, and interventions to ameliorate these downstream health impacts. In addition to a number of NIH institute or center (IC) NOSIs, OBSSR also has issued a trans-NIH NOSI to address common areas of interest across ICs and provide a mechanism for ICs to fund urgent competitive revisions and administrative supplements without publishing their own NOSI.

To sort by title, organization, dates or announcement number, click the table headers below.

Title	Announcement Number	Issuing Organization	Opening Date	Closing Date
Notice of Special Interest (NOSI) regarding the Availability of Administrative Supplements and Urgent Competitive Revisions for Mental Health Research on the 2019 Novel Coronavirus	NOT-MH-20-047	NIMH	3/27/2020	4/16/2021
Notice of Special Interest (NOSI) regarding the Availability of Administrative Supplements and Urgent Competitive Revisions for Research on the 2019 Novel Coronavirus	NOT-DA-20-047	NIDA	3/19/2020	3/31/2021
Notice of Special Interest (NOSI) regarding the Availability of				

- Adherence to mitigation
- Mitigation risk reduction
- Economic impacts
- Social impacts
- Downstream health impacts
- Interventions to ameliorate impacts
- Healthcare access
- Natural experiments

https://obssr.od.nih.gov/research-support/funding-announcements/

Skate to where the puck is going

How to:

- Optimize unwinding of mitigation to maintain lower transmission rates while improving economic and social recovery
- Provide services to the backlog of “elective” care
- Help families manage complicated bereavement
- Reduce COVID-19 recovery complications
- Communicate risk in the context of better therapeutics, vaccines
- Minimize vaccine hesitancy, especially given the rapid pace of vaccine development and testing

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Questions? Bill Riley:
william.riley@nih.gov

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@OBSSR.NIH

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