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Future directions of multiple behavior change research

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Abstract Non-communicable diseases (i.e., chronic diseases including cardiovascular disease, cancer, chronic respiratory disease, diabetes and obesity) result in 36 million deaths each year. Individuals' habitual participation in a single health-risk behaviors substantially contribute to morbidity and mortality (e.g., tobacco use, daily fast food intake, etc.); however, more concerning is the impact of typically co-occurring or clustering of multiple health-risk behaviors. This burden can be minimized through successful cessation of health-risk behaviors and adoption of healthy behaviors; namely healthy lifestyle adoption or multiple health behavior change (MHBC). MHBC is a developing field and future research recommendations are provided to advance MHBC research. A valid measure of MHBC (i.e., lifestyle) is warranted to provide the needed basis for MHBC investigations and evaluations. MHBC is thought to occur through shared co-variation of underlying motivating mechanisms, but how these relationships influence behavior remains unclear. A better understanding of the relationship between behaviors and the related motivating mechanisms (and potential cross-relationship of influences) is needed. Future research should also aim to improve lifestyles through understanding how to change multiple health behaviors. Finally, MHBC research should target the development of sustainable interventions which result in lasting effects (e.g., capacity, systems, policy and environmental changes), with dissemination considered during development. Focusing MHBC research in these areas will increase our understanding and maximize the impact on the health of populations.

Keywords Multiple health behavior change · Behaviors · Future · Research

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Multiple health behavior change rationale

Non-communicable diseases (i.e., chronic diseases) are non-infectious diseases or medical conditions that result in 36 million deaths each year; the most deadly chronic diseases include cardiovascular disease, cancer, chronic respiratory disease, and diabetes (World Health Organization [WHO], 2013). Specific to the U.S., chronic disease is the leading cause of death, contributing to 70 % of all deaths among adults (Kung et al., 2008). Furthermore, chronic disease related medical costs significantly contribute to the consistent annual rise in U.S. health care expenditures (Hodgson & Cohen, 1998; Thorpe & Philyaw, 2012).

Chronic disease is strongly associated with numerous *health behaviors*, such as diet, physical activity, smoking,

and excessive alcohol intake (Ford et al., 2009). Unfortunately, more than 1/3 of adults do not meet national recommendations for physical activity (National Center for Health Statistics, 2011); and 38 % and 23 % of Americans consume <1 serving of fruits and <1 serving of vegetables daily, respectively (McGuire, 2013). Furthermore, 19 % of Americans 25 years or older are current tobacco smokers (National Center for Health Statistics, 2011) and 30 % of adults report excessive alcohol use (Naimi et al., 2007).

Individuals' habitual participation in a single health-risk behavior can seriously contribute to morbidity and mortality (e.g., tobacco use, daily fast food intake, etc.); however, more concerning is the typical *co-occurrence or clustering of multiple unhealthy behaviors*. For instance, most adults report habitual participation in more than one health-risk behavior (Fine et al., 2004; Poortinga, 2007; Pronk et al., 2004). For example, tobacco use co-occurs with numerous other health-risk behaviors, including excessive alcohol use and physical inactivity (Fine et al., 2004; Pronk et al., 2004). Similarly, individuals practicing unhealthy dietary habits are also typically inactive (Emmons et al., 2005). This type of unhealthy lifestyle strongly contributes to preventable chronic disease (Sacks & Katan, 2002; Tuomilehto et al., 2008), and is the strongest contributor to mortality (Bagnardi et al., 2000; Berrigan et al., 2003; DiSipio et al., 2006; Key et al., 2004; Sacks & Katan, 2002; Tuomilehto et al., 2008) and increasing health-care costs (Shinton, 1997; Edington, 2001).

This burden can be minimized through successful cessation of health-risk behaviors and adoption of healthy behaviors; namely healthy lifestyle adoption or *multiple health behavior change (MHBC)* (Haapanen-Niemi, Vuori, & Pasanen 1999). MHBC is estimated to reduce chronic disease by 68 to 71 % (Ford et al., 2009), improve humans' quality of life (Harrington et al., 2010), and save over $16 billion in U.S. annual medical costs (Levi, Segal, & Juliano, 2008). In light of these benefits, a better understanding of what motivates individuals' healthy lifestyle (i.e., multiple health behavior research) is emphasized in current public health research.

MHBC interventions are defined as addressing two or more health behaviors either simultaneously or sequentially within a limited time period (Prochaska, 2008). A behavior may be conceptualized as a specific aspect with a behavioral domain such as eating fruit, vegetables, fiber, sugar, salt, fat, fast food, etc., or it may be conceptualized as the behavioral domain itself such as eating healthy. Therefore MHBC research includes relationships across and/or within well-defined behavioral domains.

The current purpose is to summarize some of what is known about effective MHBC research and promotion, as well as provide future directions to advance the field. Five specific current MHBC topics are discussed, with relevant recommendations for future research: (1) MHBC measurement; (2) MHBC predictors; (3) MHBC theory/mechanisms; (4) methodology of MHBC intervention/promotion; and (5) the dissemination (or scalability) of the MHBC efforts. The ultimate goal is to progress the MHBC field to improve the prevention and management of non-communicable diseases. To lay the basis for the five topics presented in the following sections, the impact of MHBC is presented. This includes an evidence-based foundation for why future research needs to be focused on the aforementioned MHBC areas. This is followed by a discussion and call for research addressing the five topics.

Impact of MHBC

Health and health-risk behaviors refer to actions that influence health, and MHBC is hypothesized to have a greater impact on health and well-being than changing a single behavior alone (Prochaska et al., 2008). This impact can be either negative (e.g., tobacco, sugar, salt and fat consumption) or positive (e.g., physical activity adoption and increased fruit and vegetable consumption). Given the co-occurrence of common health behaviors, MHBC research should focus on *comprehensive lifestyle promotion* for multiple health behaviors. In a systematic review of 220 studies from 1990 to 2013, King et al. (2015) report that most MHBC interventions use a randomized controlled trial (RCT) design (62 %). Studies targeted diet and physical activity (56 %) in the general population (14 %) or population subgroups (45 %); and, many of these promotional efforts were highly successful.

Previous MHBC interventions reported success when targeting participants' adoption of more than one healthy behavior. For example, individuals progressing towards smoking cessation also increased their physical activity (French, Hennrikus, & Jeffery, 1996) and decreased their alcohol use (Unger, 1996). More specifically, one RCT found that individuals who adopted one healthy behavior were up to 5-times more likely to adopt an additional healthy behavior (Johnson et al., 2008). Successful MHBC promotion has also been documented among diverse populations and contexts; including successful MHBC among postmenopausal women with type-2 diabetes (Toobert et al., 2007), Japanese male smokers (Nagaya et al., 2007), primary care patients (Prochaska et al., 2005), and worksite employees (Velicer et al., 2004). However, the majority of MHBC interventions were carried out in the U.S. (49 %), with only a few studies conducted in the Middle East (2 %), Africa (0.5 %), and South America (0.5 %); and only a small number of studies conducted among young adults (1 %), or racial and minority ethnic populations (4 %) worldwide (King et al., 2015). While there is much

research from Europe (e.g., De Vries et al., 2014; Ernsting et al., 2013; Fleig et al., 2011, 2014, 2015, Grant, Wardle, & Steptoe, 2009; Harrington et al., 2010; Keller et al., 2008; Kremers et al., 2004; Lippke et al., 2015; Poortinga, 2007; Van Nieuwenhuijzen et al., 2009) transferability to emerging regions of the world is not clear. Although promising, the implementation and dissemination of MHBC efforts are not yet well established. For MHBC research to reach full potential in the prevention of chronic disease, consistent methodology is needed and certain associations must be better understood.

MHBC measurement

Reported outcomes of MHBC interventions suggest high effectiveness and likelihood to advance the public health impact; however, initial methodological groundwork is required to generate empirical evidence to support or refute these suggestions (Prochaska et al., 2008). Some evidence indicates variability in the prevalence of health-risk behaviors and associated health consequences based on age, sex, ethnicity, body mass index (BMI), socioeconomic status (SES), and education-level (Lantz et al., 2010). For instance, the higher prevalence of health-risk behaviors among individuals of lower SES does not fully account for the majority of the relationship between SES and mortality. Additionally, being overweight/obese may protect against mortality for individuals 55 years or older (Lantz et al., 2010). A valid measure of multiple health behaviors (i.e., lifestyle) among diverse populations is warranted to provide the needed basis for MHBC investigations and evaluations.

To test the relationship among certain lifestyle recommendations and translation to behavior, Wilson et al. (2015) report a meta-analysis consisting of 150 research reports. The studies reveal a curvilinear association between the number of recommendations and improvements in behavioral and clinical indicators. Specifically, outcomes demonstrate that interventions promoting a moderate number of behavioral recommendations report the highest likelihood of change. Therefore intervention outcomes may be influenced by the number of behaviors targeted (Wilson et al., 2015) and targeting too many health behaviors may be overly demanding for participants. On the other hand, promotion of limited behavioral recommendations may facilitate lifestyle changes that are too easy and/or less meaningful. Interestingly, Wilson et al. (2015) also discuss how this non-linear relationship is more evident among samples with low motivation to change (e.g., non-patient populations, nonclinical settings, and non-expert facilitators); similar examinations among diverse populations and within contexts is warranted. Clearly, development of the most effective MHBC interventions requires a greater understanding of the most appropriate number of behaviors to target within a single intervention.

The lack of a measurement consensus also impedes MHBC research. Therefore, psychometric examinations and population comparisons are recommended to determine the appropriate methodology for a comprehensive lifestyle metric. Health behavior interventions historically include separate measures for each health behavior targeted, leading to multiple significance tests that inflate the Type I error rate and complicate data reporting (Prochaska et al., 2008a). To accurately evaluate the effectiveness of interventions assessing MHBC, advanced methods are needed to quantify and report valid changes across several health behaviors (i.e., lifestyle improvements). For instance, within interventions addressing more than one health behavior (e.g., nutrition and physical activity), an aggregated measure of the behaviors will be more informative of health outcomes than individually testing the effects of single behaviors (Lippke et al., 2015). In addition, multi-model analyses are more advanced than traditional MANOVA or ANCOVA analyses. Examinations using latent models that control for measurement error are recommended, such as latent true change and latent structural equation model analyses.

Along with intervention evaluation, a validated lifestyle metric would permit outcome comparisons across both single behavior and multiple behavior examinations (Prochaska et al., 2008b). A comprehensive metric will inform policymakers and healthcare practitioners the most efficient distribution of resources to maximize health improvement (Nigg et al., 2002; Woolf, 1999). Although aggregation of multiple health behaviors into a single comprehensive influence has been applied in previous research, these metrics need further evaluation. The majority of interventions have assessed health behaviors as separate entities (Nigg et al., 2002), using inconsistent measurement scales that limit program evaluations and study comparisons. Thus, little is known about the most effective way to assess MHBC (Emmons, 2000; Smedley & Syme, 2001). For example, we are currently unable to distinguish the health effects of smoking one cigarette versus performing one 30-min bout of physical activity. A more comprehensive understanding of how distinct health behaviors impact non-communicable disease is crucial for development of efficient and effective MHBC measurement and promotion.

Factors influencing MHBC

It is generally understood that common health-related behaviors are associated, or interrelated. Typically, the higher the probability of one behavior, the higher the probability for the other (Grant, Wardle, & Steptoe, 2009;

Nigg et al., 1999); however, some behaviors interrelate more highly than others. Empirically, high correlations have been found between diet and exercise ($r = .36$ by Boudreaux et al., 2003; $r = .14$ by Keller et al., 2008; $r = .16$–$.26$ by Lippke et al., 2012), as well as between smoking and alcohol consumption ($r = .35$; Keller et al., 2008; $r = .07$; Lippke et al., 2012). Conversely, low or no association was reported between non-smoking and exercise and fruit and vegetable intake (Clements Thompson et al., 1998). Low to no correlations were found between alcohol consumption and diet ($r = -.06$; Keller et al., 2008; $r = -.03$; Lippke et al., 2012), alcohol consumption and exercise ($r = .05$; Keller et al., 2008; $r = .06$; Lippke et al., 2012), exercise and non-smoking ($r = .11$; Boudreaux et al., 2003; $r = -.09$; Keller et al., 2008; $r = .21$; Lippke et al., 2012), and diet and smoking ($r = -.11$; Keller et al., 2008; $r = .16$; Lippke et al., 2012).

Evidence suggests strong associations between health-promoting behaviors and between health-risk behaviors. Abrantes et al. (2009) report adolescent participants involved in sport are more likely to attempt smoking cessation, while those not attempting to quit tobacco are more involved in high-risk sexual activity. Within the same sample, smoking cessation efforts are inversely related to physical activity and positively associated with alcohol use; specifically, adolescents who report alcohol use were 66 % less likely to report successful smoking cessation (Abrantes et al., 2009). Similarly, Van Nieuwenhuijzen et al. (2009) report weak associations between health-promoting and health-risk behaviors. Among young adults (16–22 year olds), Verkooijen, Nielsen, and Kremers, (2009) report a negative correlation between physical activity and smoking. Evidence also suggests variability in associations between multiple health behavior based on age and gender (Van Nieuwenhuijzen et al., 2009; Verkooijen, Nielsen, & Kremers, 2009), requiring further examination.

It is clear that related health behaviors correlate or cluster; but, even more interesting is recent evidence suggesting cross-behavioral associations between multiple health behaviors and certain motivating constructs. Previous research reports a significant relationship between physical activity self-efficacy and fat intake, and between physical activity outcome expectations and fat intake (Grembowski, 1993). Additional research shows physical activity self-efficacy being related to individuals' progression towards adoption of regular fruit and vegetable intake (Lippke, Nigg, & Maddock, 2012). In fact, evidence suggests certain theoretical constructs are more strongly related to health outcomes than the behaviors themselves (Kremers et al., 2004). This may be an important area for future examinations, as a greater understanding will facilitate more efficient MHBC interventions.

Recent evidence on cross-behavioral associations supports MHBC occurring through shared co-variation of the underlying motivating mechanisms; yet, how these relationships influence behavior remains unclear. Examination of relationships between cross-behavioral mechanisms has been limited to cross-sectional research, which does not account for inter-correlations or change (Blakely et al., 2004; Kremers et al., 2004). A better understanding of these relationships is essential to informing effective future interventions, providing insight into how individuals move towards MHBC. Hence, using certain theory-based constructs to promote one health behavior may have a positive influence on other behaviors; thus, promoting both behaviors more efficiently (King et al., 1996). Longitudinal examinations with holistic statistical analyses (e.g., structural equation modeling) are recommended to more clearly understand these relationships.

Theoretical conceptualizations of MHBC

The design of effective MHBC intervention requires theoretically driven approaches and increased empirical evidence (Amato, Park & Nigg, 2016; Wilson et al., 2015). However, evidence regarding the effective mechanisms of MHBC is currently lacking. A better understanding of the relationship between behaviors and the related motivating mechanisms (and potential cross-relationship of influences) is needed. Examinations are also needed to explain how some individuals are capable of successfully changing one behavior (while unconsciously changing another) whereas other individuals are not. A call for theory and evidence-based research is timely, and an example for such a theory is the Compensatory Carry-Over Actions Model (CCAM; Lippke, 2014; Fig. 1). Two factors conceptualized in the CCAM are presented below which describe psychological mechanisms unique to multiple behavior change.

Compensatory cognitions as key in MHBC

Compensatory cognitions are based on the Compensatory Health Beliefs (CHBs; Knäuper et al., 2004). CHBs are beliefs that certain unhealthy (but pleasurable) behaviors can be compensated for by engaging in other healthy behaviors (Knäuper et al., 2004). Theoretically, CHBs influence one's decision to engage or not engage in a certain behavior. In short, the choice to indulge in a health-risk behavior elicits compensation by performing a healthy behavior. For instance, one might believe than eating a second helping (consuming additional calories) or smoking can be compensated by exercising more later on.

Growing evidence supports the relationship between cognitive processes and CHBs. Long-term smokers are

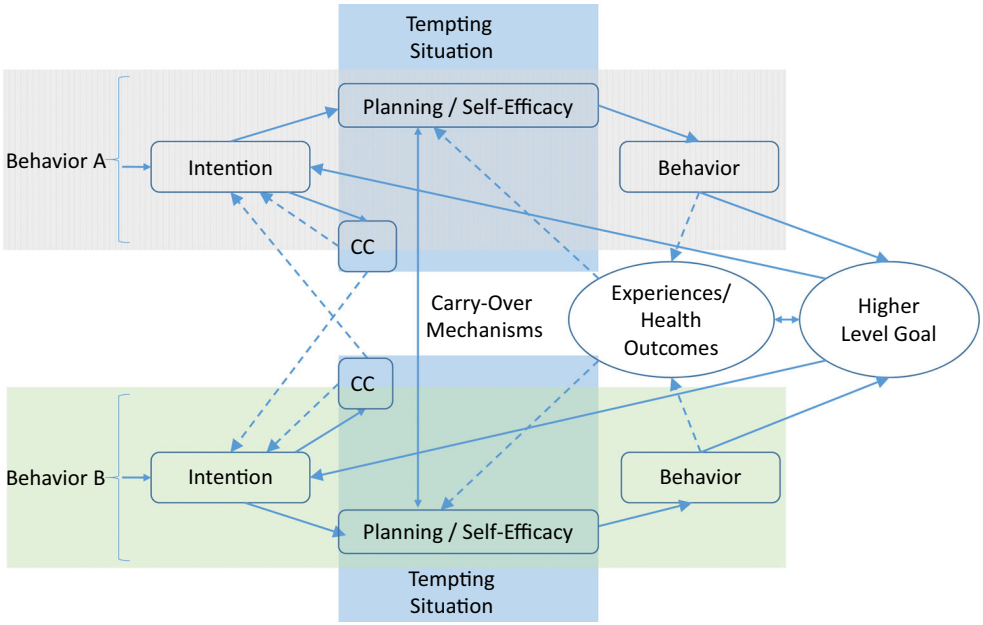

Fig. 1 Compensatory carry-over action model (CCAM; Lippke, 2014)

more physically active compared to short-term smokers, which may be a consequence of long-term smokers' rationalization that engaging in physical activity alleviates breathing difficulties associated with tobacco use (Xu, 2002). The risk of such compensatory beliefs occur when an individual truly believes one behavior will compensate for another (e.g., eating cookies now and working out at the gym tonight), thereby increasing the likelihood of not translating goals into behavior (not eating cookies). Among dieting women, tempting situations hamper participants' success (Kronick & Knäuper, 2010). This is especially evident when compensatory intentions are formed; specifically, intentions to perform a compensatory behavior increase participants' risk to perform behaviors contradictory to diet-related goals (Kronick & Knäuper, 2010). Ernsting et al. (2012) researched the role of compensatory cognitions about occupational flu shot participation among field workers at-risk for exposure to flu infections. An intervention aiming at increasing flu shot participation by a planning intervention was implemented with the company. Results show that the intervention is only successful in those individuals with low compensatory cognition (i.e., low on the belief that people are vulnerable for catching a flu if they are regularly active and eat healthy). Thus, hindering compensatory cognitions should be addressed.

Related to future MHBC research, specific impacts of individuals' behavioral compensation needs to be further investigated. The frequency of success when individuals attempt to overcompensate for a behavioral relapse by exaggerating the practice of another health behavior (e.g., indulge in fast-food and over-exercise) and the impact of these compensation behaviors on health requires further investigation. Moreover, examinations are needed to explain the effect of healthy behavioral relapse on the adoption or maintenance of another health behavior. Another factor unique to MHBC addresses how learning achievements in one behavior domain can be transferred to another domain. This is described by the Carry-Over Mechanisms (COM).

Carry-over mechanisms (COM) are also known as Transfer (Barnett & Ceci, 2002) or Spill-Over (Mata et al., 2009). One can measure COM as a mechanism carrying over resources from one domain to another, or in terms of one behavior serving as a gateway for another (Dutton et al., 2008; Fleig et al., 2011, 2014, 2015). Experiences, skills, knowledge and self-efficacy can be carried-over to different behaviors and domains. While a substantial amount of research exists on transfer in educational and occupational areas, studies in the health behavior domain testing transfer and comparable concepts are comparatively few.

Preliminary findings on COM stem from studies investigating correlations of behaviors or clusters of individuals. One such study is that by Lippke et al., (2012), in which one group of participants perform some behaviors at an optimal level (e.g., physical activity) and are motivated to change the ones that were sub-optimal (e.g., nutrition). From this, one might assume that individuals are carrying-over their motivation (to perform physical activity on a regular basis) to change other behaviors as well (nutrition). Another group of study participants maintain all behaviors optimally, so presumably have already carried-over all

needed cognitions, resources and skills. Selective evidence suggests that cognitive transfer and behavioral outcomes mainly occur with physical activity resources transferred to nutrition behaviors. For instance, in the studies by Fleig et al. (2011, 2014, 2015) a transfer from strenuous and moderate physical exercise in minutes per week to numbers of fruit and vegetables per day is shown. However, no study could be found explicitly targeting transfer in a RCT, testing its effect in contrast to an active control group. This needs further attention in the future to have clear recommendations on how to support evidence based carry-over processes in MHBC.

MHBC interventions

To have the highest impact on health, changing two or more behaviors at the same time, and in concert with each other is imperative (Prochaska, Wright, & Velicer, 2008). Such lifestyle changes consist of altering different behaviors or different behavioral aspects. The behaviors most influential on health are non-smoking, nutrition and physical activity (Mokdad et al., 2004). More specifically, examples of different behavioral aspects of physical activity are volitional physical exercising and active commuting. Nutrition may comprise aspects such as consuming vegetables and fruits, whole-grain, high-fiber foods, fish, and limited sugar, fat and salt (Lichtenstein et al., 2006).

To explore this concept further, Webb et al. (2010) report on 85 internet-based interventions. The aggregated effect is rather small ($d = 0.16$), but significant, with 10 Interventions targeting multiple behaviors revealing a mean effect of $d = 0.12$, and 75 Interventions targeting a single behavior showing a mean effect of $d = 0.17$.

In two comparable meta-analyses, the effect sizes for single behaviors like physical activity are not significant with $d = 0.24$. Effects for healthy eating are between $d = 0.15$ and 0.20; and smoking cessation between $d = 0.07$ and 0.33. This indicates that it appears difficult to find one general efficacy of behavior change interventions and that studies in the past are better in changing single behaviors than multiple behaviors. Thus, it might be more difficult to change multiple behaviors, but it is possible, and should increase the public health and individual gain factors more strongly than single-behavior interventions. Therefore, future research should aim to improve lifestyles: i.e., to change multiple health behaviors instead of just one.

To find out more about the specific content of MHBC interventions compared to single health behavior change interventions, McSharry et al. (2015) compares the *number and type of behavior change techniques* (BCT, Michie et al., 2015) in single health behavior change interventions addressing obesity versus MHBC interventions addressing obesity. There are a greater number of physical activity behavior change techniques ($M = 11.7$) in MHBC interventions in comparison to single health behavior change interventions ($M = 8.7$), which is quite impressive as the MHBC interventions also targeted diet. However, the study did not research the effectiveness of the two, as this was a secondary data analysis. This type of research on the techniques of effective MHBC research can inform intervention strategies and potentially increase applicability across behaviors.

An ongoing question in the MHBC intervention domain is whether it is more effective to change the different behaviors at the same time (*simultaneously*) or only one unhealthy behavior after the other (*sequentially*). This was done in a study by De Vries et al. (2014). The authors tested a web-based Tailored Multiple Behavior Change Intervention in a 2-year RCT with $N = 5055$ individuals. All study participants received recommendations regarding physical activity, vegetable and fruit consumption, alcohol intake and smoking. While the sequential condition appeared more effective after 1 year, the simultaneous condition appeared more effective after 2 years. The authors conclude from this finding that "a combination of both tailoring strategies may be most suitable for multiple behavior change" (De Vries et al., 2014, p. 1). Despite some successes, MHBC research is currently stunted by inconsistent result reporting and other methodological issues. Systematic research focusing on methods and results reporting is called for.

Dissemination of MHBC efforts

Increasing dissemination and implementation of efficacious MHBC interventions should be a focus of research (Amato et al., 2016; Green et al., 2015). MHBC research should target the *development of sustainable interventions which result in lasting effects* (e.g., capacity, systems, policy and environmental changes), with dissemination considered during development. RE-AIM (Reach, Efficacy, Adoption, Implementation, and Maintenance) is a framework to guide such efforts (Glasgow et al., 1999). This recommendation for sustainable interventions with lasting effects is not specific to MHBC research but is more important for the MHBC field due to the increased and broader impact on chronic diseases. Transferable competencies such as self-efficacy and planning should be incorporated which enable transfer to related behaviors. Coping with interbehavioral inhibitors such as compensatory cognitions and failed mastery experiences are also recommended to be incorporated into interventions to minimize these effects.

To achieve the previously mentioned research recommendations, e.g., to test the putative mechanisms in longitudinal studies and randomized controlled trials, scientist in this area will need to adapt the way they work. This

opens the opportunity to increase the involvement in, the impact of, and the knowledge base about MHBC. Communication across disciplines and research topics needs to improve. Other disciplines, such as computer and internet science (i.e. ICT) and informatics with artificial intelligence could add significantly to our filed in times of digitalization (e.g., Lippke et al., 2015).

MHBC research should make use of inter- and transdisciplinary approaches, especially by planning and conducting research projects and transferring findings to real life. Exchange with colleagues at conferences and events, and by publishing in interdisciplinary journals is recommended to have an impact above and beyond established silos. As these interdisciplinary partnerships develop and grow, a vision of the MHBC field must also advance, and include a strategic plan for the growth of MHBC science. Researchers should investigate complementary hypotheses that employ new and comparable methods. Furthermore, MHBC experts should plan workshops within their institution or their professional societies to make explicit MHBC science goals and benchmarks. This should focus on sharing identified strengths/assets/resources (e.g., measurement tools) and fostering future collaboration.

Discussion and conclusion

While many research and practical initiatives are aiming at improving MHBC, much more evidence needs to be collected about measurement, predictors, and theoretical explanations of co-occurrences of different behaviors. More emphasis is also needed on the underlying micro factors (i.e. psychological variables and mechanisms), meso factors (social-cognitive and environmental variables and mechanisms), as well as macro factors (societal and policy variables and mechanisms) interrelating with MHBC in correlational and interventional designs. If we better understand the enabling and hindering factors across these levels of MHBC, we can convince other researchers, practitioners and policy makers to focus more on MHBC. This will improve MHBC research, application, and dissemination, in order to ultimately help individuals more efficiently and effectively adopt and maintain MHBC. This will require interdisciplinary and ambitious approaches.

Compliance with ethical standards

Conflict of interest Karly Geller, Sonia Lippke and Claudio R. Nigg declare that they have no conflict of interest.

Human and animal rights and Informed consent All procedures followed were in accordance with ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all participants included in the study.

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