

Master Thesis:

Customization in eHealth – The application of customization in behavioural change interventions aimed at improving physical activity and dietary behaviour

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## Abstract

**Background/ Objectives:** The field of eHealth has experienced huge growth during the past decade. One of its most popular areas are interventions focused on nutrition and physical activity. A problem is that these interventions cannot cause long-term behavioural changes in users. One possibility to improve this maintenance is to adapt interventions to the individual user. Customization is a new approach to user adaption, which has become a relevant topic in research during the past years. This research aims to explore customization, in the context of eHealth fitness- and nutrition interventions, to draw a comparison between research and practice.

**Method:** For this purpose, two studies were executed. Study 1 consisted of a systematic literature review, examining customization and similar approaches to user adaption in current literature on eHealth nutrition- and physical activity interventions. Five databases including Google Scholar, Scopus, PsycINFO, and IEEE were searched. Studies were included when they encompassed a behavioural change intervention, mentioned customization or a similar user adaptation approach, addressed a general adult population, were published in the past fifteen years, and were written in German or English. In total, 18 studies met the criteria and were included in the review. In Study 2, a content analysis of currently available nutrition- and fitness-focused apps was executed, using a coding scheme that was developed from the results of Study 1. Apps were included in the analysis if they were placed in the Health and Fitness category of the iTunes app store, focused behavioural change related to nutrition, diet, or physical activity, and addressed a general adult population. In total, 21 apps were considered in the content analysis.

**Results/ Conclusion:** The results of Study 1 show that customization is not a clearly defined construct across research yet. From the current perspective, customization can be understood as an approach to user adaption which specifies itself by providing users with more autonomy in comparison to other user adaption approaches. The findings of Study 2 show that there is an overlap between current research on customization and its application in practice, but only to a moderate extent. Future research is recommended to focus on the development of a clear, unified definition of customization. Further, higher accordance between research and practice appears to be advisable to develop more successful behavioural change interventions in the field of eHealth.

## **Introduction**

The purpose of this research was to explore customization in the context of electronic health interventions focused on physical activity and dietary behaviour. During the past decade, such interventions have become a popular tool for the improvement of different health-related behaviours. A problem hereby remains that interventions fail to establish long-term behavioural changes among users (Kwasnicka, Dombrowski, White & Sniehotta, 2016). One way to improve interventions in this regard appears to be the adaption of an intervention to the individual user. Customization is a recent approach to user adaption which has gained increased attention during the past years (Bol, Hoie, Nguyen, & Smit, E., 2019). This research considers the definition and function of customization in currently available literature and examines how scientific concepts and approaches related to customization are implemented in practice.

### **General Background**

Electronic Health, often abbreviated as eHealth, can be defined as "the use of emerging information and communication technology, to improve or enable health and health care" and is a sector that experienced huge growth during the past decades (Oh et al, 2005). This rise has been caused by multiple factors, which are amongst others: the increasing use of information and communication technologies, growing access to the internet across the whole world population, rising interest for health-related topics in many communities, and the opportunity of delivering behavioural health interventions in a highly efficient manner (Müller et al. 2018).

eHealth solutions are also used to change health behaviour. In the past years, an increasing number of technological behavioural health interventions have been published which have become a popular tool to achieve a healthier way of living (Ballantine & Stephenson, 2011). Such interventions are available for a wide range of behaviours and aim for example to support users while quitting smoking, dealing with a chronic illness, improving their mental health, during a diet, or for increasing physical activity (Oosterveen, Tzelepis, Ashton & Hutchesson, 2017). Research assessing different types of behavioural change interventions has shown that such interventions function as an effective way of modifying different health related behaviours (Kwasnicka et al., 2016).

Interventions aimed at the improvement of behaviours related to nutrition, diet, and physical activity belong to the most popular in the field of eHealth and have developed to be a widely used tool for reaching a healthier weight (Ballantine & Stephenson, 2011). This development is an advantage as obesity is a highly prevalent issue in our society and has been

found to cause different health problems related to physical as well as psychological well-being (Darmasseelane et al. 2014; Adair & Lopez, 2020). Physical inactivity and unhealthy nutrition are risk factors for several diseases e.g. cardiovascular diseases, diabetes, different cancer types (Thomas et al, 2017).

The use of eHealth interventions to combat obesity has positive as well as negative sides. The main advantage of such interventions is their cost-effectiveness. They can be delivered to a huge scope relatively easy and fast, which makes them more affordable than intervention approaches delivered in a face-to-face setting (Vandelanotte et al. 2016). Further, different studies have shown that they function as an efficient tool for changing behaviours related to nutrition and physical activity (Hobbs et al., 2013; Tsai & Wadden, 2005; Vandelanotte et al. 2016). However, a disadvantage of the interventions seems to be that the behavioural change reached through them lacks sustainability. Research evaluating long-term effects of the interventions shows that positive effects tend to be reduced over time and behavioural changes are not long-lasting (Kwasnicka, et al., 2016). Participants may show success during and in the first months after an intervention but experience high levels of relapse one or two years after the intervention (Tsai & Wadden, 2005).

Therefore, a great number of interventions aimed at behavioural change are currently available to users, but these are lacking the ability to create behavioural change in the long-term (Kwasnicka et al., 2016). This is problematic because there is clearly a need for the development of cost-effective weight-loss interventions to affect the global burden of obesity and related diseases, but currently available interventions can only reduce this burden to a limited extent by not causing long-term behavioural changes and experiencing high rates of relapse among participants (Vandelanotte et al. 2016).

When taking into consideration what is needed to improve interventions in this regard, an important factor appears to be the personalisation of interventions, by adapting them to the individual user (Bol et al., 2019). A study by Hobbs et al. (2013) for example, found that behavioural interventions focused at increasing physical activity appear to be more successful when they included a form of user adaption as in this case individual tailoring, in comparison to interventions which did not include such. This view is supported by Vandelanotte and colleagues, who mentioned in their work from 2016, user adaption to be a factor that contributes to the effectiveness of eHealth interventions.

One approach to user adaption in interventions is the 'customization' of interventions, a newly established concept across research on behavioural interventions. Customization can be defined as 'the ability to self-tailor the mediated environment to match one's individual

preferences' (Bol, Hoie, Nguyen, & Smit, E., 2019, p. 2). It differs from conventional user adaption by involving the user actively in the personalisation process, so that user adaption is not executed automatically by the system but the user himself. An example for customization would be to let users adapt the interface of a mobile application through adding or removing features (Bol et al., 2019).

User adaption through customization is useful for different purposes, of which one is promoting learning, especially for health-related behaviours. A successful learning experience is essential to reach behavioural change. Customization contributes to an effective learning experience by providing a certain extent of autonomy to the learner (Bol et al., 2019). To make this relationship between autonomy and learning for technological interventions more clear, two theories are introduced in the following part.

### **Theoretical Framework**

The individual's need for autonomy is central to learning according to several theories, including Self-Determination Theory (SDT) (Deci & Ryan, 2012). SDT assumes that three aspects lay the basis for an individual to be autonomously orientated towards a goal, which are competence, relatedness, and autonomy. Hereby autonomy describes people's need to self-regulate behaviours related to the learning experience, relatedness refers to the need to have meaningful relationships with others and competence considers the need to experience a certain extent of effectiveness during interaction with one's environment (Levesque-Bristol & Yu, 2020).

Fulfilment of these three aspects contributes to a self-determined motivation which promotes a positive and successful learning experience. A higher perceived autonomy during learning, therefore, seems to enhance the learners' motivation. Although the level of preferred autonomy tends to differ between individuals, autonomy was found to contribute to an enhanced learning process and improved learning outcome (Bol et al., 2019).

To understand the role of autonomy for successful learning in eHealth interventions the motivational technology model can be used. This model is based on the self-determination theory and assumes that providing feelings of autonomy, relatedness, and competence to the user as essential for health technologies to work and promote successful behavioural change. Hereby, the feeling of competence is produced through the navigability of a technology, relatedness through interactivity, and autonomy through customization.

Navigability refers to the user interface of a technology and determines how easy it is for users to orient themselves on it (Wojdyski & Kalyanaraman, 2015). Interactivity

considers the interaction between user and system by describing the responsiveness of a system to the user's input (Fan, Liu & Wang, 2016). Fulfillment of these factors leads to that users establish an intrinsic motivation, leading to a positive engagement with the health content, which promotes a change in attitude and behavioural intention of health behaviour (Bol et al., 2019).

Considering these two theories it gets clear that customization is a factor affecting the motivation of participants in behavioural change interventions (Sundar, Bellur & Jia, 2012). Furthermore, the theories demonstrate how customization could be used to address the problem of creating long-term behavioural change in e-Health interventions. Increasing the autonomy of learners through customization, increases the motivation of participants, which facilitates the learning process and leads to the development of more successful and sustainable interventions.

The preceding description of the current situation of eHealth interventions aimed at physical activity and dietary behaviour shows, that such interventions provide a great chance for the development of cost-effective health care for the treatment and prevention of obesity, but strike for an improvement in their long-term effectiveness. Currently available research and the aforementioned theories point in the direction of approaches to customize interventions as one possible solution for making interventions more effective.

Therefore, this research aims to explore customization as a new approach to user adaption more in-depth through dealing with its application in eHealth interventions focused on behaviours related to nutrition and physical activity. For this purpose, two studies will be executed. In the first study, a conceptual framework for customization will be developed through examining customization and further approaches to user adaption in current research on eHealth nutrition- and physical activity interventions. The second study focuses on the application of user adaption in practice, through a content analysis of currently available nutrition- and fitness-focused apps. The central question addressed in this research can be formulated as: *"How is the current state of customization as an approach to user adaption in eHealth interventions aimed at improving physical activity and dietary behaviour?"*

## **Study 1 - Conceptual framework for customization in behavioural change interventions: a systematic review**

The previous introduction shows that customization has become a relevant term in behavioural research, especially for the field of eHealth. However, looking at current literature it is striking that different terms are used by researchers to describe what has been defined as customization by Bol, Hoie, Nguyen, and Smit in their study from 2019. Examples of such terms are amongst others: tailoring, individualisation or personalisation of interventions; for all the common goal is to offer more individualised interventions that are adapted to the user's needs, provide a higher extent of autonomy to the participants, and are therefore more successful in changing health-related behaviours (Chatzitofis et al., 2017; Greenwell & Hoare, 2016; Kaptein, 2019). Therefore, a specified and universal description of customization is lacking, it appears to be not a clear defined construct across research yet.

This raises the question how customization as a concept can be understood for research, what is encompassed by it and how it can be differentiated from other, similar approaches such as tailoring. Bol and colleagues who explored customization and its effects in mobile applications for the improvement of physical activity, made first attempts in a similar direction by differentiating customization from traditional tailoring approaches. They proposed that, although tailoring aims to fit an intervention to the user's needs, customization considers doing this to a higher individualised and personalised extent and goes beyond traditional tailoring approaches by offering the user to take active control over the content of the intervention. A further attempt for such a distinction comes from Sundar and Marathe (2010), who state that the difference between tailoring and customization lies in the manner of personalisation. For tailoring, personalisation is system-initiated and therefore happens automatically, whereas personalisation through customization is user-initiated, which means users need to take action themselves to personalise a technology.

The prior introduced theoretical framework shows, that gaining a deeper and better understanding of customization may be an important factor for improving the long-term effectiveness of eHealth interventions focused at dietary behaviours and physical activity (Bol et al., 2019; Sundar, Bellur & Jia, 2012). Related to that, this research aims to address the issue of defining customization in the specified context, eHealth interventions aimed at improving dietary behaviours and physical activity, through a literature review in which the definition of customization and related terms is explored more in-depth and a clearer overview of customization is developed. Therefore, the research question addressed in this study can be formulated as:

*"How can customization be understood in the context of behavioural change interventions aimed at improving physical activity and dietary behaviour?"*

## **Methods**

For the purpose of understanding customization in the context of behavioural change interventions addressing physical and dietary behaviours, a systematic review of relevant literature was executed following the PRISMA Guidelines for Systematic Literature Reviews (Moher, Liberati, Tetzlaff & Altman, 2009).

### **Search Strategy**

Relevant literature was identified by searching articles on different scientific online databases. Accordingly, the databases Google Scholar, Scopus, PsycINFO, and IEEE were searched. Next to the term customization, other search terms that describe processes aimed at adapting technologies to the individual user were used in combination with search terms for physical and dietary behavioural interventions (Figure 1). The search was conducted on April 7, 2020.

Criteria for a study to be included were that (1) the study addresses a behavioural change intervention aimed at improving physical change dietary behaviour or weight loss, (2) the study addresses customization, either by mentioning customization directly or another term describing the personalisation process of a technology, (3) the study addresses a general adult population as a target group, (4) the research was published during the past fifteen years, (5) the research is available in German or English language and (6) the study is published as primary literature.

Studies that addressed a non-adult population as a target group, treated weight loss in a target group with a specific disease, were not available in English or German language, were published before 2005, or were not published as primary literature were excluded in this research. For this study, no protocol was submitted.

### **Figure 1.**

*Search terms.*

<i>Customization, tailoring, personalization, interactivity, navigability, individualization</i>	<i>OR</i>
<i>behavioral change, fitness, diet, physical activity, weight management, weight loss, exercise</i>	<i>AND</i> <i>OR</i>
<i>e-Health, m-Health, behavioural intervention</i>	<i>AND</i> <i>OR</i>

## **Data Analysis**

After searching the selected databases with the afore-described search terms all search results were processed further, except for the database Google Scholar, where only the first 200 results were considered, to limit the broad range of results this platform offers to the most relevant studies (Bramer, Rethlefsen, Kleijnen & Franco, 2017).

In the next step, duplicate articles were removed, using the software EndNote X9. Afterward, all abstracts of the remaining articles were screened and articles that did not meet the predefined inclusion and exclusion criteria were sorted out. The remaining articles were again evaluated for fulfilling the criteria, considering their full-text version. All articles that fulfilled the criteria after this step was included for the qualitative analysis.

## **Data Extraction**

Pre-defined data of the reviewed articles were collected and tabulated using Excel 2003. These data included basic information pertaining author and publication date as well as aspects of the study's methodology and setting, which were participant characteristics, study design, and intervention characteristics, the main outcome, strengths and limitations of the study as described by the original authors and the conclusion which could be drawn from it.

To consider the concept of customization in the different studies, four specific characteristics related to customization were extracted from the reviewed articles. These included (1) the terminology used to describe customization or personalisation of a technological intervention in the study, (2) the definition of these terms, (3) the implementation of customization in the intervention used, and (4) the eventual outcomes or effects regarding the application of customization in an intervention (Appendix A).

## **Quality Assessment**

The methodological quality of the reviewed studies was assessed using the "checklist for measuring study quality" that was published by Downs and Black in 1997. The full version of the checklist is included in the Appendix (Appendix C). In line with previous studies, the ambiguous item regarding statistical power was modified to indicate the presence of a statistical power analysis or sample group calculation by allocating 1 (present) or 0 (absent) points (Dekkers, Melles, Groeneveld & de Ridder, 2018). For each study, a quality score and a mean score were calculated. The quality score was ranked on a 4-category scale: poor (<15), moderate (15-19), good (20-24), and excellent (>25) as done in a similar study by ten Haaf

and colleagues (2018). This assessment was used to get a general impression of the quality of the included studies, but it did not influence whether a study was included.

## **Results**

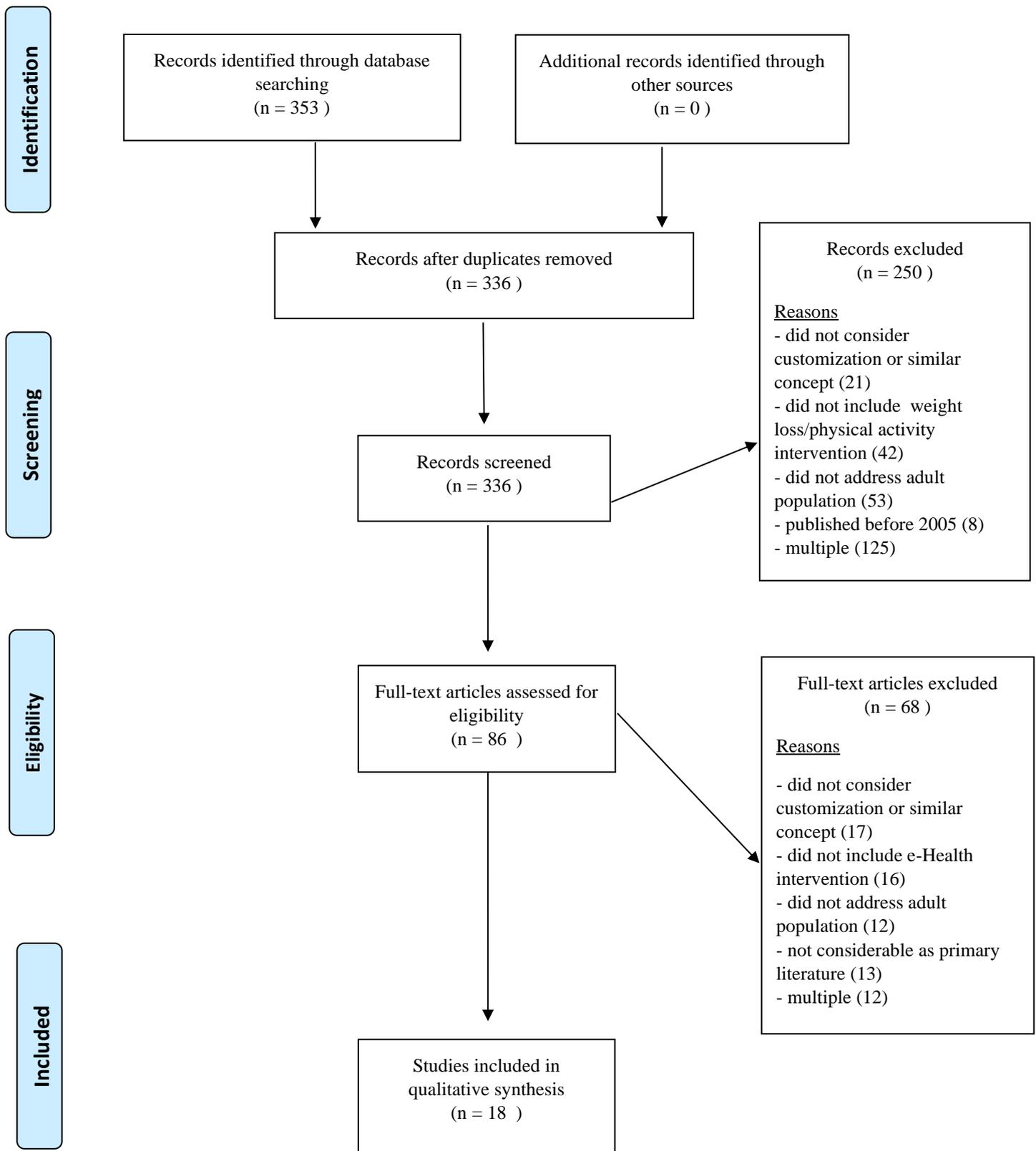
### **Study Selection**

An overview of the study selection process is displayed through the PRISMA flow chart (Figure 3). In total 353 publications were identified from four different databases, of which 336 remained after removing the duplicates. In the next step abstracts were screened for fulfilling the inclusion criteria, whereas 250 articles were excluded; 21 due to not addressing customization or a similar concept, 42 because of not considering an intervention aimed at weight loss, physical activity, or improved nutrition, 53 due to not addressing an adult population as a target group, 8 through being published before 2005 and 125 for more than one of the aforementioned reasons.

The remaining 86 articles were assessed considering their full-text version for their eligibility for the study. During this process 68 articles were excluded; 17 because they did not consider customization or similar concepts, 16 as they did not address an e-Health weight loss or physical activity intervention, 12 as they did not address an adult population, 13 due to not being considerable as primary literature and 10 because of multiple of the aforementioned reasons. In total, 18 articles were considered as eligible and therefore included in the review.

**Figure 3.**

Prisma Flow Chart of the selection process for eligible articles.



*Note.* Inclusion criteria are: (1) the study addresses a behavioural change intervention aimed at improving physical change dietary behaviour or weight loss, (2) the study addresses customization, either by mentioning customization directly or another term describing the personalisation process of a technology, (3) the study

addresses a general adult population as target group, (4) the research was published during the past fifteen years and (5) the research is available in German or English language.

### **Characteristics of studies included in the review**

All 18 references included in the review were journal articles, of which a list is displayed in the Appendix (Appendix B). The most common study type of the reviewed articles were randomized controlled trials, in total nine studies used this study design (3, 4, 7, 8, 12, 14, 15, 16, 18) whereas one study was a protocol for a randomized controlled trial (9). Other study designs included were the analysis of log data (1, 13), a cross-sectional online survey (2), usability evaluation (5), prototype development (6, 17), interview study (10) and a case study (11). Most interventions included participants of all genders except for three studies of which two only included female participants (2, 12) and one only male participants (14). The age of the participants ranged from 18-80 years.

All articles included an intervention aimed at improving behaviour related to nutrition or physical activity, which was delivered completely or partly through a technological device. Such technological devices were for 50% of the interventions of a computer programme or website (3,5,6,8,10,12,14,16,18) and a mobile phone application for the remaining interventions (1,4,7,9,11,13,15,17). In one of the studies both types of devices were included; hereby the intervention was delivered via smartphone and website to the participants (2).

All reviewed interventions addressed the goal of behavioural change in similar ways, by offering participants a programme aiming at improving physical activity, nutritional habits, weight or all of them. In most programmes a goal is defined at the beginning, which the participant tries to reach during the intervention. The intervention supports the participant to reach this goal, through different behavioural change techniques for example self-monitoring, sending reminders, or providing relevant information to the participants (1, 2, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 16, 17, 18).

An example of an intervention is the ENGAGED programme, which consists of a smartphone app that aims to support its users during weight loss. In the intervention, users can set individual goals related to weight loss. Furthermore, the app includes a function to track calories and physical activity so that users continuously receive feedback on their progress (4). Three out of 18 articles addressed interventions that applied relatively divergent, specialised approaches in comparison to the interventions addressed in the other articles (3, 5, 10). Those interventions differed from the others concerning the intervention design as participants were not addressed through a goal-focused programme. One of these interventions was an exergaming platform that aimed to deliver appropriate physical activity tasks for elderly people through specifically designed games (5). The other two interventions

focused on direct interaction with participants: in one intervention a computerized personal trainer was implemented for this purpose (3) and the other intervention provided an enhanced way of communication between participants and a real-life dietician (10).

### Quality Assessment of included studies

An overview of the scores for the assessed categories and the quality scores of the studies is provided below (Table 1.). Generally, the quality scores of the assessed studies fell in three of the four categories, which are: poor, moderate, and good. Hereby, the study of Morgan and colleagues reached the highest quality score (24), and the study by Koskinen and colleagues the lowest (17). The mean scores for each category can be found in the Appendix (Appendix D, Table 4). The mean scores for items in the category reporting were high to moderate, except for items addressing the reporting of confounders and adverse events. Other, strikingly low scores were found for items related to the blinding of subjects or assessors and data dredging.

**Table 1.**

*Quality of included studies assessed with the Downs & Black Checklist.*

Author (ref.)	Reporting (maximum score = 10)	External Validity (maximum score =3)	Bias (maximum score = 7)	Confounding (maximum score = 6)	Total (maximum score = 27)	Quality as per cut-off described
Klein et al. (1)	3	1	2	0	5	Poor
Hutchesson et al. (2)	7	2	3	1	13	Poor
Canevello et al. (3)	4	2	2	4	12	Poor
Pelligrini et al. (4)	4	3	2	4	13	Poor
Konstantinidis et al. (5)	8	2	1	5	16	Moderate
Melchart et al. (6)	2	1	3	2	8	Poor
Hebden et al. (7)	8	3	1	5	17	Moderate
Friederichs et al. (8)	9	3	4	4	20	Good

Table 1  
continued

Author (ref.)	Reporting (maximum score = 10)	External Validity (maximum score =3)	Bias (maximum score = 7)	Confounding (maximum score = 6)	Total (maximum score = 27)	Quality as per cut-off described
Duncan et al. (9)	8	3	3	4	18	Moderate
Barnett et al. (10)	8	3	4	4	19	Moderate
Phatak et al. (11)	8	3	5	5	21	Good
Moultapa et al. (12)	4	3	2	5	14	Poor
Yoganathan et al. (13)	1	0	2	0	3	Poor
Morgan et al. (14)	8	3	7	6	24	Good
Korinek et al. (15)	6	3	4	4	17	Moderate
Vandelanotte et al. (16)	7	3	5	3	18	Moderate
Vandelanotte et al. (16)	7	3	5	3	18	Moderate
Koskinen et al. (17)	3	0	1	0	4	Poor
Spittaels et al. (18)	5	3	4	4	16	Moderate

## Customization in the reviewed articles

### *Definition of customization*

As mentioned before, studies that used diverse terms for describing customization or similar processes were included in the review. The most used term was tailoring which was mentioned in 17 articles (1,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18), whereas the term customization itself was mentioned in three articles (10,13,17). Other terms used were personalize/ personalization (1,2,7,11,12,14), individualize/individualization (2, 12, 15) and interactivity (4,8,16).

Nine out of 18 reviewed articles defined the term that was used

(1,3,5,10,12,13,15,17,18). An example of a definition is provided in the article of Michel, Klein, Manzoor, and Mollee from 2017 where the term tailoring is described as "the process of adapting the content of the app to the individual needs of the user" (1). A similar definition for tailoring can be found in the article from Patrick and Canevello from 2011, which is "adapt an intervention to individuals' needs and experiences throughout the process of learning a new health behaviour". A definition example for a different term comes from the article of Barnett and colleagues from 2015 where personalisation is described as "matching the participants' motivational needs".

The definitions that were used had in common that they referred to the adaptation of a technology to the user's specific needs related to motivation, information or experiences concerning a certain behaviour. Only one paper provided a different definition, it defined tailoring as "adapting the intervention to the needs of elderly people" which means that for this case the adaption does not take into account the individual user but the whole target group (5).

### ***Application of customization***

The interventions introduced in the articles described different options for the adaption to the individual user (Table 3). One option, that was used in all interventions, was the possibility for users to define or choose goals they wanted to reach by using the intervention. For example, the "MyPace" intervention introduced in the article of Barnett and colleagues (10), asked participants to define the main goal, describing what they want to achieve through participation in the intervention, and smaller intermediate goals, describing the actions they need to take to reach their main goal.

Another option that was used often was to provide the user with personalised feedback (10). Personalised feedback took the form of a text message, an email, a notification, a call, or a personal conversation with a trainer (1, 2, 3, 6, 7, 8, 9, 10, 13, 17). One way to tailor feedback to the individual user was for example to mention the user's name or individual progress in the feedback message (1,7).

Furthermore, many interventions also provided users with the possibility of self-monitoring, whereby users track their physical activity or nutrition to monitor their own progress in the intervention (1, 2, 4, 6, 9, 10, 11, 13, 15, 16). Whereas most interventions offered tracking of nutrition or physical activity via a log directly in the application or on the intervention website, two interventions provided users with physiological feedback of a smartwatch (Fitbit) which could be connected with their mobile phone application (8,15).

An approach employed in fewer interventions was to assess the needs and conditions of

users before the start of the intervention for example during an interview or through a questionnaire, in order to adapt the intervention based on the information of this assessment (1, 6, 9, 11, 18). A more technological approach than interviews or questionnaires to assess the user's needs has been used in two interventions (11, 15). Hereby, user data was collected and stored in the intervention app to create a personal ID. This was used to develop a dynamic model of the user's physical activity with which the intervention was adapted in a systematic and scalable way to the user (11). An example of this is the use of a so-called system identification (system ID) in the physical activity intervention "Just Walk" (11), which aimed to increase walking among its participants. Participants received a new step goal every day which was adapted to the user through the use of system ID. Hereby all data inputs of the previous days are considered to assess the user's individual performance and circumstances to provide the ideal step goal for the current day to the user.

A relatively different approach was found in one of the two studies explicitly mentioning the word customization. This intervention offered users to adapt the intervention on a technological level through "end user development"; hereby users can choose between different configuration packages, make modifications to application settings, make adaptations to the interface and the way information is represented to them and modify data themselves (17). An example of end-user development is displayed below; users can adapt the interface by entering variables they would like to track with the app (Figure 2).

Another rather distinct option for user adaption was found in one intervention that tried to enhance their users' motivation through higher levels of interactivity by including features in the intervention which are also included in social networks and provide therefore opportunities for shaping the intervention more individually. Users had for example the opportunity to create an own profile page, connect virtually with other participants to share their own results and progress and to connect the intervention with their usually preferred social networking site, for example, Facebook or Instagram (16).

A further outcome related to the application of user adaption was that the reviewed interventions differed regarding the extent of autonomy provided to users. Autonomy in the considered context did not only relate to an intervention being adapted to the user, but that individual choices are offered along with the adaption. Examples for choices would be interventions offering users to choose which parameters they would like to track or how they would like to track their progress by connecting an own tracking device (11, 13, 18).

**Figure 2.**

*Example of end user development. Users can adapt the interface through modifying the displayed variables. Retrieved from: 17.*



**Table 3.**

*Application of user adaption in the reviewed articles.*

Category	User Adaption	User adaption with a higher extent of (user) autonomy
<i>Feedback &amp; Reminders</i>	Feedback is provided to users in the form of individually tailored messages. (18)	Users are asked for consent before receiving information or feedback. (8)
	Feedback is personalised by addressing the user with his or her name, including the user's individual progress or connecting to the user's personal goals. (1, 7, 14)	Users have the possibility to rate feedback. (1)
	Reminders are sent to the user based on his or her location, so that they are received at a time point where the user can directly take action. (12)	Users are provided with additional, optional feedback opportunities as for example a quiz (9)
	Feedback is provided to users by a real person which functions as their personal (diet) assistant. (10,14) Feedback is adapted to the user's fitness level. (18)	

Table 3  
continued

Category	User Adaption	User adaption with a higher extent of (user) autonomy
	Interaction between user and technology takes the form of a motivational dialogue. <sup>A</sup> (8)	
	Feedback is provided based on a quiz which assesses current knowledge level of the user. (2,9)	
	Feedback is provided to users by a computerized personal trainer or virtual coach (1,3).	
	Users receive daily records and/ or weekly summaries of their individual progress. (3, 9)	
	Users receive reminders for self-monitoring via email and SMS. (9)	
	Users receive real-time feedback to monitor their performance. (12)	
<i>Self-monitoring</i>	Users can self-monitor parameters like weight, diet, or exercise. (14, 4, 2, 7, 10, 9, 12, 16)	Users can choose an own tracking device and connect it with the intervention app. (11, 1, 13)
	The intervention app can be connected to a Fitbit (11)	Users have the possibility to self-monitor progress online or offline with downloaded and printed materials, providing a choice for more discretion. (6)
		Users have the possibility to track good and bad days, in order to reflect on differences between them. (10)
		Users have the possibility for self-evaluation and reflection on their goals. (13)
		Users can choose which parameters are tracked or measured in the intervention app. (17)

Table 3  
continued

Category	User Adaption	User adaption with a higher extent of (user) autonomy
<i>Goals</i>	Users receive rewards for their achieved goals in form of points in a point system. (15)	Users can adapt the included meal plan to their individual diet. (9) Users have the option to reflect on their own progress with help of video tutorials. (8)
	Users have the possibility to choose a preferred intervention goal out of a predefined set of goals. (1,7,18, 9, 10).	Users can adapt goals to their individual fitness level. (13)
	Users receive daily step goals which are adjusted based on individual progress. (11,15)	Users can set individual goals related to diet, calorie intake or physical activity. (4, 2, 13)
<i>Other</i>	Intervention is tailored to individual use through an assessment of the individual needs and circumstances before or during the intervention. (1, 6, 8, 12, 18)	Users have the possibility to add new features to the app. (17)
	An individualised gaming experience is provided to the user, whereby the games are adapted to his or her abilities. (5)	Users have the possibility to adapt the user interface. (17)
	System ID is used to adapt the intervention to the user. (11)	Users have the possibility to add data from external devices. (17)
	User received recommendations for exercising based on visited locations, using GPS tracking. (1)	Users have the possibility to enable/ disable features of an app for example health parameters (17)
	User has the possibility to create an own profile page and become virtually friends with other participants of the intervention. (16)	User has the possibility to connect the intervention to social networks (16)

<sup>A</sup>Dialogue is simulated between user and programme, in which the user answers questions, receives tailored follow-up questions and tailored feedback.

### ***Effects & Outcomes of interventions included in the reviewed studies***

Taking into consideration the outcomes and effects of the reviewed behavioural change interventions, most articles reported positive effects on the intervention health outcomes as well as on user's motivation and satisfaction related to the intervention itself (1, 4, 6, 9, 11, 12, 13, 14, 15, 18). Hereby, the main outcome ten out of eighteen studies reported was related to the overall effect of the intervention which means it was a behavioural change related to

nutrition or physical activity or weight loss among participants in general (2, 4, 5, 6, 11, 12, 14, 15, 16, 18).

Three of eighteen studies reported as their main outcome the utility of a theoretical approach for designing a behavioural change intervention. In all three articles, the tested interventions were based on principles of the self-determination theory, which was found to enhance the participants' motivation and therefore contributed to the design of more successful interventions. Therefore the main outcome in these articles did not only relate to the effectiveness of the interventions in general but also showed how the self-determination theory can be successfully applied in an intervention design (3, 8, 13).

Main outcomes that are directly related to user adaption in an intervention were only found for three out of eighteen articles. Those indicated that the integration of user adaption in an intervention design and thus provide a high level of adaptation to the individual user, leads to more successful interventions (1, 10, 17). None of the reviewed articles statistically tested the effect of user adaption. One study, which was the only study that explicitly mentioned the term customization, questioned the extent of personalisation that was offered to the user as being too high and therefore overstrain users (17).

## **Discussion**

In order to explore the research question "*How is customization understood in the context of behavioural change interventions aimed at improving physical activity and dietary behaviour?*" a systematic review considering different aspects of customization and other approaches to user adaption for behavioural change interventions was executed. Studies were reviewed for the term used to describe customization processes, their definition of customization, the implementation of customization in an intervention, and the effect personalisation had for the intervention. In total, 16 studies describing interventions focused on changing behaviours related to nutrition or physical activity, were included in the review.

In the following part, the most important results of this review will be discussed, to apply the conclusions which can be drawn from this research in a further study (Study 2). Hereby, only aspects related to customization directly are considered. An overall discussion, taking into consideration all aspects of this study follows in the last section of this paper (General Discussion).

### **Application of user adaption**

While the way user adaptation was applied in an intervention differed, there were certain elements among the reviewed interventions for which user adaptation seemed to be most

common. These elements include: goals, feedback, and self-monitoring. Hereby, "goals" refers to the reason users have for taking part in an intervention and their intentions related to that. Possibilities to adapt an intervention ranged from being able to choose a preferred goal out of a preformulated set of goals (1,7,18, 9, 10) to the possibility of defining an own goal which the user would like to reach (4, 2, 13). The second element, "feedback", describes a possibility for the interaction of the intervention with the user, through sending reminders and providing feedback on the users' performance during the intervention. Feedback refers mostly to the users' progress related to physical activity, nutrition, or weight loss (18). Hereby, the adaption to the user was applied mostly through using personalised feedback messages (1, 7, 18) that included aspects as the user's name, progress, or goals. A small number of interventions offered the possibility to rate the feedback (1) or asked users for their preferences if and how they would like to receive feedback (8, 9, 12).

The last element "self-monitoring" considers the possibilities users have to track their own process during an intervention. Hereby, most interventions offered the possibility to track the most important variables related to behavioural change such as weight, diet, or exercise (14, 4, 2, 7, 10, 9, 12, 16). Approaches that offered a higher extent of user adaptation can be found for example in form of the possibility of connecting an intervention to an own tracking device (11, 1, 13) or the possibility to define for oneself which parameters one would like to track (18).

### **Defining customization**

One of the main goals of this research was to explore how customization is defined in the context of behavioural change interventions aimed at dietary behaviour and physical activity. Due to customization being a relatively new, not yet established term across research, different terms referring to the personalisation of a technology were included in the review as well.

As expected, a broad range of terms was used to describe ways to adapt a technological intervention to the user, whereas customization appeared to be one of the lesser-used terms. The term that was used most often and appeared to be the most established term to describe the personalisation processes of an intervention is tailoring. Although a broad range of terms was used, a closer look at the definition of the different terms showed that all referred to a similar concept: "adaption of a technology to the individual user". This definition appears to be the key idea behind the term tailoring as well as behind the term customization.

Taking into consideration the results of this review, it is difficult to provide a clear, distinctive definition of customization in the considered context. One reason for this is that

customization itself has been hardly mentioned: only two studies used this term. Thus, it can be concluded that several terms are describing similar processes of user adaption, amongst them customization.

Although an explicit description of the difference between customization and tailoring is not provided in the reviewed articles, it gets clear from this research that both concepts have in common that they refer to user adaption in a technological intervention. However, what differentiates customization from tailoring is the extent of autonomy provided to the user. Therefore, it can be concluded that customization may refer to higher-level approaches of user autonomy, whereas tailoring refers to approaches that offer fewer choices to users. This conclusion is in line with the statements on tailoring and customization from the literature introduced in the introduction, which state that customization individualises an intervention to a higher extent and is user-initiated, whereas tailoring is system-initiated (Bol, Hoie, Nguyen & Smit, 2019; Sundar & Marathe, 2010). It can be summarised that our findings are congruent with existing literature and thus match our idea of customization from the start of this research.

To illustrate this finding, the following continuum for user adaption in interventions is proposed (*Figure 4.*). The continuum ranges from no user adaption to full user adaption, with tailoring included in the middle and customization included at the upper end of the continuum. The main idea behind this continuum is to summarize the fact that adaption to users in interventions is currently described by a whole range of terms and possible to different extents. As tailoring appears to be the most common term regarding this topic and customization is the term of interest for our research, both terms were included in relation to each other on the continuum.

**Figure 4.**

Continuum of user adaption.



## **Autonomy**

As mentioned previously, it is difficult to provide a unified definition for customization in the considered context, based on the current results. Also, a clear distinction between tailoring and customization as described in the introduction was not found in the reviewed articles. Therefore, the question arises of how and if customization is distinguishable from other approaches, based on the results of this review.

One aspect which should be considered in this regard is autonomy. As shown in the results and the previous section, interventions differed regarding the extent of autonomy provided to users. It is striking that interventions using approaches which offer more autonomy to users, used the term customization rather than tailoring (17, 18). For example, the intervention in the study from Spittaels, Bourdeaudhuij, and Vandelanotte (2007) that provided most individual choices to users, in comparison to all other reviewed interventions. This finding indicates that customization might be distinguishable from other approaches to user adaption, by providing a higher extent of autonomy to users.

### **Study 2: Content Analysis of customization applied in currently available diet- and fitness-focused apps**

Study 1 has investigated customization as a concept in current literature on behavioural change interventions aimed at improving nutrition and physical activity. An overview of how customization is currently understood and applied in interventions developed for research was established. To extend this view, this study aims to explore customization in an additional context: direct-to-consumer mobile health applications that were developed directly for the market. An understanding of customization in this context broadens the perspective on customization as a concept and gives an overview of the level of agreement between current research and available interventions.

Mobile health interventions, so-called mHealth interventions, are delivered to users via mobile phone applications. mHealth has become increasingly popular in the past decade as the use of smartphones and similar devices has grown across the whole world population (Oh et al, 2005). One branch of mHealth are fitness and nutrition apps, which aim to increase physical exercise, promote healthier nutrition, or support weight loss among users (Ballantine & Stephenson, 2011).

The market for such applications has experienced a rise during the past years so that fitness- and nutrition applications belong to the most popular mHealth products currently. In 2018 fitness apps were the most commonly used among adult health app users in the U.S.

with 78% having used them in the past 12 months, followed by nutrition apps with 34% (Kunst, 2020). This shows that these apps have developed to be a relevant branch in the eHealth sector and are therefore a fitting example to explore customization in a direct-to-consumer related context.

As mentioned before, customization appears to be a new, not yet established construct across research (Bol et al., 2019). From the perspective of Study 1, customization can be defined as a form of user adaption that offers users more autonomy in comparison to more conventional approaches, as for example tailoring. Exploring customization in a direct-to-consumer context will provide insights into how and if customization is currently implemented in practice. Further, a comparison between the newly established definition of customization for research and its level of agreement practice can be drawn.

Study 1 described how behavioural change interventions often experience problems related to long-term improvements in users. This problem also applies to fitness- and nutrition apps as users tend to improve their habits related to physical activity and nutrition during the first weeks of app usage, but often fail to improve them for long term (Rivera et al., 2016). Due to this, it is crucial to improve currently available apps about the user's motivation, for example through a higher extent of customization.

The goal of this research is to extend the results of Study 1 and offer a comparison between customization in research and practice. Therefore, the results on customization produced in Study 1 are used as a basis for this study. To explore customization in a direct-to-consumer related context currently available, popular fitness- and nutrition-focused applications are analysed. The second research question can be formulated as: "*How is customization implemented in direct-to-consumer fitness and diet mobile health applications?*"

A coding scheme examining how and if customization is applied in the considered apps, will be developed. The development of a coding scheme appears appropriate to answer the research question as currently no instrument exists to measure the implementation of customization in eHealth interventions. Further, developing a coding scheme based on the outcomes of Study 1 enables a direct comparison between research and practice.

## **Methods**

### **App Selection**

To consider the application of the concept customization in the context of behavioural diet-

and fitness interventions in practice, we analysed the most popular mobile applications to improve nutrition and fitness-related behaviours that are currently available in the iTunes App Store.

Apps were included in the analysis if they (1) were placed in the Health and Fitness category of the iTunes app store, (2) addressed behavioural change related to nutrition, diet, or physical activity, (3) were ranked in the most popular apps for the Health and Fitness category and (4) addressed the general population and were not designed for a target group with a specific illness. The popularity of an application was determined through the rank of the application in the iTunes app store, which was used in other studies for similar purposes and has developed to be an accepted measure for popularity in this context (Azar et al., 2013).

### **Content Analysis**

The selected applications were first coded for basic descriptive information, which included the applications' name, price, and rank in the iTunes App Store. Then, every app was coded according to the behaviour it aimed to influence using the Health Education Curriculum Tool (HECAT), which was already applied for a similar purpose in a study by West and colleagues (2012). In their study, the content areas of the HECAT were used to sort applications into categories based on the behavioural change they aimed to achieve. As this research focused on behavioural change interventions related to nutrition, diet, or physical activity, only two categories of the HECAT content areas were included for analysis which were "Healthy Eating" and "Physical Activity" (Figure 5).

In the next step, the applications were coded for the extent of customization they provided to users, using a coding scheme that has been developed based on the results of the previously done systematic review. The coding scheme considers a distinction between conventional approaches to user adaption as for example tailoring and novel approaches like customization, by assuming that customization provides a higher extent of autonomy to users than conventional user adaption (see Study 1). The development process and a closer description of the coding scheme are provided in the next section.

### **Figure 5.**

*HECAT content areas for the categories "Healthy Eating" and "Physical Activity".*

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HECAT Content Areas

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#### **Healthy Eating**

Calorie Counters, journals, logs

Healthy Recipes and cooking tips  
Healthy diet-specific information  
Nutritional breakdowns of specific food items

### **Physical Activity**

Workouts, tips, ideas  
Parks, facilities, directional maps  
Race announcements, events  
Monitors, measurement of workouts, logs, automatic recordings

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## **Coding Scheme**

### ***Conceptualization***

The main conclusion of Study 1 was used as a starting point for the development of the coding scheme. It is therefore based on the assumption that customization can be understood as an extended approach of tailoring that provides a higher extent of autonomy to users. Whereas tailoring refers to more conventional and system-initiated approaches to personalise a technology, customization displays a newer approach that includes user-initiated adaption. Tailoring entails adaption of a technology to the individual user while customization aims to provide users with autonomy over the adaption, for example through individual choices for the intervention they participate in. Both approaches to user adaption were considered in the coding scheme.

### ***Development of the coding scheme***

We developed the coding scheme using the article of Michie and Prestwich (2010) on the development of a theory-based coding scheme as a guideline. First, the considered articles of Study 1 were reviewed a second time, focusing on the application of tailoring and customization. The results of this review built the first template of the final coding scheme (Table 3). It was concluded that there are three main categories for which tailoring and customization were applied in the reviewed interventions, which are 'Feedback & Reminders', 'Self-monitoring', and 'Goals'. All other elements that could not be categorized were summarised in the section 'Other'. Therefore, four categories for user adaption were established for the final coding scheme (Figure 6). In the next step elements related to each category were listed, to have an overview of how adaption was applied in the four categories. For the category "Feedback & Reminders" user adaptation was for example done through adapting the feedback messages to the individual user by integrating the user's name, progress or goals. In this category, customization could include asking users if they would like to

receive feedback or not, as done in the study of Friederichs and colleagues from 2015, or offering users additional, optional feedback possibilities (Duncan et al., 2018).

In the next category "Self-Monitoring" user adaption happened through offering the possibility to receive real-time insights in one's progress (Moultappa et al., 2011) or adapting meal plans to one's individual diet (Duncan et al., 2018). An example for user adaption with a higher extent of autonomy in this category would be that users receive the possibility to choose how they would like to self-monitor data, with an application, an additional device, or on paper (Phatak et al., 2018; Klein, Manzoor & Mollee, 2017; Yoganathan, Duwaraka, Kajanana & Sangaralingam, 2013; Melchart et al., 2016). The third category "Goals" offers user adaption through altering one's goals to the individual fitness level (Yoganathan et al., 2013), whereas user adaption with a higher extent of autonomy could take the form of self-formulated goals related to calorie intake, physical activity and diet (Pelligrini et al., 2012; Hutchesson et al., 2016; Yoganathan et al., 2013).

Other approaches for user adaption which were found and did not belong in one of the pre-defined categories were amongst others, to assess the individual needs and circumstances of users before or during the intervention with assessments or questionnaires and adapt an intervention based on these (Klein et al., 2017; Melchart, et al., 2016; Friederichs, Oenema, Bolman & Lechner, 2015; Moultappa et al., 2011; Spittaels, Bourdeaudhuij, & Vandelanotte, 2007). User adaption with a higher extent of autonomy was done by providing the users with the possibility of adding new features to an app or adapting the interface of the application (Koskinen & Salminen, 2007).

Based on these insights, the items for the final coding scheme were formulated. Hereby the distinction between customization and tailoring was considered, as well as the four categories and related user adaption elements. Each element was reformulated into an item with two response options. Therefore each item describes an element related to user adaption so that the coder decides after reading the item if the described element is included in the particular app or not.

### ***Final Coding Scheme***

The final coding scheme consists of 28 items in total (Figure 6.). The items are sorted into two main sections, which are "Tailoring" and "Customization", in each section items are grouped in one of the four categories "Feedback & Reminders", "Self-Monitoring", "Goals" and "Other". For each item, two response options are given which are: (1) included and (2) not included.

The first section "Tailoring" included 16 items of which six fall in the category "Feedback

& Reminders", one belongs to the category "Self-Monitoring", three belong in the category "Goals" and six fall into the category "Other". The second section "Customization" included 12 items of which three are grouped into the category "Feedback & Reminders", four fall into the category "Self-Monitoring", two are sorted in the category "Goals" and three are categorized as "Other".

**Figure 6.**

*Final coding scheme for content analysis.*

<i>Item</i>	<i>Included</i>	<i>Not included</i>
<b>Tailoring</b>		
<b>Feedback &amp; Reminders</b>		
Personalised feedback and reminders; messages include for example name, gender, progress, goals.		
Feedback from personal (diet) assistant, virtual coach or a computerized personal trainer.		
Feedback is connected to personally relevant advice or information.		
Feedback based on knowledge assessment, for example through a quiz or questionnaire.		
Regular summaries of individual progress (for example on a daily or weekly basis).		
Reminders to self-monitor own performance.		
<b>Self-monitoring</b>		
Self-monitoring of personal performance as for example weight, diet, exercise, calories, steps etc.		
<b>Goals</b>		
Goals are adapted to the user’s individual fitness level.		
Reward system for achieved goals.		
Users can choose preferred goals out of a set of predefined goals.		
<b>Other</b>		
Intervention is adapted to the user's needs through an assessment before or during the intervention.		
Gamification of personalised content to enhance user's motivation.		

<i>Item</i>	<i>Included</i>	<i>Not included</i>
Users receive recommendations based on progress (as stored in a personal ID).		
Users receive recommendations based on location (GPS tracking).		
Intervention can be connected to social networks as for example Instagram, Facebook etc.		
Intervention has a social network character (e.g. users can create an own profile page in intervention).		

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### ***Customization***

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#### **Feedback & Reminders**

Users are asked for consent before sending information (including but not limited to consent for reminders or feedback).

Users have the possibility to rate feedback.

Additional, optional feedback options (for example, a quiz).

#### **Self-Monitoring**

Users can connect application to own tracking devices.

Users get the possibility to choose how they would like to track data (for example online or offline).

Users have the possibility for self-evaluation and reflection of own progress.

Users can adapt the meal plan to their individual preference (for example by choosing a vegetarian diet).

#### **Goals**

Users can formulate own goals related to diet, calorie intake or physical activity.

Users can make an own action plan and reflect on their own progress and the intervention provides guidance to do so (for example through video tutorials)

#### **Other**

Users have the possibility to add new features to the intervention.

Users have the possibility to adapt the user interface.

Users have the possibility to enable or disable features in the app.

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## Results

### Interrater Reliability

The interrater reliability of the coding scheme was assessed through an assessment of the apps MyFitnessPal and Strava by two additional persons. Both persons were master students so that a basic understanding of research methods and the usage of a coding scheme can be assumed. For the app MyFitnessPal, Cohen's Kappa was found to be .60 and for the app Strava .46. Therefore the interrater reliability can be considered as moderate, in both cases (McHugh, 2012).

### Content Analysis

#### *Included Applications / Categorization (HECAT)*

In total, 21 apps from the 'Health and Fitness' section of the iTunes app store were included in the content analysis. An overview of the included apps and their rank in the popularity section of the app store is provided below (Table 4). Every app was categorized for the behaviour it aimed to influence, using the content areas of the HECAT (Table 5). In the next step, apps were coded for included features related to tailoring and customization, using the previously developed coding scheme.

An example of an included application is Yazio. This app supports users during weight loss and focuses hereby mainly the users' nutrition. It includes a calorie counter and provides users with healthy recipes and meal plans. But also apps focused on physical activity were included, as Adidas Runtastic, an app that offers users to track different kinds of physical activities and provides workout plans to them.

#### **Table 4.**

*Apps included in content analysis.*

<i>Name of the App</i>	<i>Rank in App Store</i>
Yazio	2
Fastic	3
Better Me	4
Adidas Runtastic	5
Strava	6

Table 4 continued	
<i>Name of the App</i>	<i>Rank in App Store</i>
MiFit	8
Life Sum	10
My Fitness Pal	11
Fit Bit	12
Body Fast	13
All Trails	14
Nike Run Club	15
Steps App	16
Very Fit Pro	19
30 Days Fitness	23
Run Keeper	24
Goals Fitness	26
Workouts Zuhause	27
Fitness Coach	29
Freeletics	34
Gymondo	36

**Table 5.**

*Results of app categorization with the HECAT.*

<i>HECAT Content Areas Score</i>	<i>Total</i>
<b>Healthy Eating</b>	
Calorie Counters, journals, logs	14
Healthy Recipes and cooking tips	8
Healthy diet-specific information	7
Nutritional breakdowns of specific food items	8
<b>Physical Activity</b>	
Workouts, tips, ideas	13
Parks, facilities, directional maps	10
Race announcements, events	6
Monitors, measurement of workouts, logs, automatic recordings	21

### ***Outcomes Coding Scheme***

The results of the content analysis with the coding scheme are displayed below (Table 6, Table 7, Table 8). The highest scores were found for the sections "Self-monitoring of personal

performance as for example weight, diet, exercise, calories, steps etc." and "Ask users for consent before sending information e.g. reminders or feedback.", as all 21 apps included those features. The lowest scores were found in sections related to the involvement of a personal diet assistant, gamification, System ID and for seven sections of the category customization, including "Give users the possibility to rate feedback." and "Additional, optional feedback options as for example a quiz." (Table 6).

Generally, apps scored higher in categories for tailoring than for customization. Comparing the results provided in Tables 7 and 8, it is striking that the maximum scores for tailoring tend to be higher than the maximum scores for customization. For tailoring, the apps 'Gymondo', 'MiFit', and 'Life Sum' scored highest, whereas the app 'All Trails' appeared to be the least tailored app. For customization, the app 'Yazio' reached the highest score, whereas four apps had the lowest score and were therefore the least customized apps (30 Days Fitness, All Trails, Run Keeper, Fitness Coach).

During the content analysis, other features were found which were related to user adaption but were not yet included in the coding scheme. One of these features was that apps offered the possibility to their users to set reminders for a preferred time or topic (Life Sum, Yazio, FitBit, 30 Days Fitness). Another option for users was to choose between different metrics to track their data e.g. choose to track weight in kg or lbs (Nike Run Club, Very Fit Pro). Lastly, two apps offered users to choose certain days during the week which they would like to use as their training days (Gymondo, Workouts Zuhause).

**Table 6.**

*Results content analysis. Total scores for tailoring and customization, per assessed category.*

<i>Item</i>	<i>Total Score</i>
<b><i>Tailoring</i></b>	
<b>Feedback &amp; Reminders</b>	
Personalised feedback and reminders; messages include for example name, gender, progress, goals.	12
Feedback from personal (diet) assistant, virtual coach or a computerized personal trainer.	2
Feedback is connected to personally relevant advice or information.	8
Feedback based on knowledge assessment, for example through a quiz or questionnaire.	1

Table 6 continued

<i>Item</i>	<i>Total Score</i>
Regular summaries of individual progress (for example on a daily or weekly basis).	17
Reminders to self-monitor own performance.	11
<b>Self-monitoring</b>	
Self-monitoring of personal performance as for example weight, diet, exercise, calories, steps etc.	21
<b>Goals</b>	
Goals are adapted to the user's individual fitness level.	12
Reward system for achieved goals.	7
Users can choose preferred goals out of a set of predefined goals.	14
<b>Other</b>	
Intervention is adapted to the user's needs through an assessment before or during the intervention.	17
Gamification of personalised content to enhance user's motivation.	1
Users receive recommendations based on progress (as stored in a personal ID).	0
Users receive recommendations based on location (GPS tracking).	9
Intervention can be connected to social networks as for example Instagram, Facebook etc.	13
Intervention has a social network character (e.g. users can create an own profile page in intervention).	11
<b>Customization</b>	
<b>Feedback &amp; Reminders</b>	
Users are asked for consent before sending information (including but not limited to consent for reminders or feedback).	21
Users have the possibility to rate feedback.	0
Additional, optional feedback options (for example, a quiz).	0
<b>Self-Monitoring</b>	
Users can connect application to own tracking devices.	0
Users get the possibility to choose how they would like to track data (for example online or offline).	0

Table 6 continued

<i>Item</i>	<i>Total Score</i>
Users have the possibility for self-evaluation and reflection of own progress.	1
Users can adapt the meal plan to their individual preference (for example by choosing a vegetarian diet).	7
<b>Goals</b>	
Users can formulate own goals related to diet, calorie intake or physical activity.	10
Users can make an own action plan and reflect on their own progress and the intervention provides guidance to do so (for example through video tutorials)	0
<b>Other</b>	
Users have the possibility to add new features to the intervention.	0
Users have the possibility to adapt the user interface.	2
Users have the possibility to enable or disable features in the app.	5

**Table 7.**

*Results content analysis, scores per assessed app for tailoring.*

<i>App (Name)</i>	<i>Tailoring - Feedback &amp; Reminders (Max. Score: 6)</i>	<i>Tailoring - Self- Monitoring (Max. Score: 1)</i>	<i>Tailoring - Goals (Max. Score: 3)</i>	<i>Tailoring - Other (Max. Score: 6)</i>	<i>Tailoring - Total (Max. Score: 17)</i>
Yazio	2	1	2	3	8
Fastic	3	1	3	3	10
Better Me	2	1	3	3	9
Adidas Runtastic	3	1	3	3	10
Strava	2	1	0	4	7

Table 7  
continued

<i>App (Name)</i>	<i>Tailoring - Feedback &amp; Reminders (Max. Score: 6)</i>	<i>Tailoring - Self- Monitoring (Max. Score: 1)</i>	<i>Tailoring - Goals (Max. Score: 3)</i>	<i>Tailoring - Other (Max. Score: 6)</i>	<i>Tailoring - Total (Max. Score: 17)</i>
MiFit	4	1	2	4	11
Life Sum	5	1	2	3	11
My Fitness Pal	2	1	2	1	6
Fit Bit	3	1	2	3	9
Body Fast	4	1	3	2	10
All Trails	0	1	1	1	3
Nike Run Club	2	1	2	3	8
Steps App	3	1	0	1	4
Very Fit Pro	3	1	0	3	7
30 Days Fitness	1	1	2	1	5
Goals Fitness	1	1	2	1	5

Table 7  
continued

<i>App (Name)</i>	<i>Tailoring - Feedback &amp; Reminders (Max. Score: 6)</i>	<i>Tailoring - Self- Monitoring (Max. Score: 1)</i>	<i>Tailoring - Goals (Max. Score: 3)</i>	<i>Tailoring - Other (Max. Score: 6)</i>	<i>Tailoring - Total (Max. Score: 17)</i>
Workouts Zuhause	1	1	2	1	5
Fitness Coach	0	1	2	1	4
Freeletics	1	1	1	3	6
Gymondo	1	1	0	0	2

*Note.* The table above provides the scoring for every analysed app for the coding scheme section "Tailoring". Scores per category and the total score are provided.

**Table 8.**

*Results content analysis, scores per assessed app for customization.*

<i>App (Name)</i>	<i>Customization – Feedback &amp; Reminders (Max. Score: 3)</i>	<i>Customization – Self- Monitoring (Max. Score: 4)</i>	<i>Customization – Goals (Max. Score: 2)</i>	<i>Customization – Other (Max. Score: 3)</i>	<i>Customization – Total (Max. Score: 9)</i>
Yazio	1	2	1	2	6
Fastic	1	1	0	1	3
Better Me	1	1	0	1	3
Adidas Runtastic	1	1	1	0	3
Strava	1	2	0	0	3
MiFit	1	1	0	0	2
Life Sum	1	1	1	0	3

Table 8  
continued

<i>App (Name)</i>	<i>Customization – Feedback &amp; Reminders (Max. Score: 3)</i>	<i>Customization – Self- Monitoring (Max. Score: 4)</i>	<i>Customization – Goals (Max. Score: 2)</i>	<i>Customization – Other (Max. Score: 3)</i>	<i>Customization – Total (Max. Score: 9)</i>
My Fitness Pal	1	1	1	0	3
Fit Bit	1	1	1	2	5
Body Fast	1	0	0	2	3
All Trails	1	0	0	0	1
Nike Run Club	1	1	1	0	3
Steps App	1	1	1	0	3
Very Fit Pro	1	1	1	0	3
30 Days Fitness	1	0	0	0	1
Run Keeper	1	0	0	0	1
Goals Fitness	1	0	1	0	2
Workouts Zuhause	1	0	1	0	3
Fitness Coach	1	0	0	0	1
Freeletics	1	1	0	0	2
Gymondo	1	1	0	0	2

*Note.* The table above provides the scoring for every analysed app for the coding scheme section "Customization". Scores per category and the total score are provided.

## Discussion

The following part discusses the most important findings of this study briefly. A broader discussion, considering all aspects related to this study and drawing a direct comparison between research and practice is provided in the last part of this paper (General Discussion).

To answer the research question "*How can customization be understood in the context*

*of behavioural change interventions aimed at improving physical activity and dietary behaviour?"* a content analysis of the most popular IOS applications in the "Health and Fitness" category was executed. The content analysis considered 21 apps for their application of tailoring and customization, whereas the results regarding the application of elements in the analysed apps were similar for both approaches. The findings suggest that elements of both approaches are applied in the analysed apps. However, not all elements for user adaption which were identified in research-based interventions were applied in the direct-to-consumer apps. Due to this, the accordance between research and practice can be described to be low to moderate.

In the direct comparison, the analysed apps included slightly more elements of tailoring than customization, which supports the assumption made in Study 1, that tailoring is the more established construct. It can be concluded that tailoring is the concept with wider popularity among research as well as in practice, compared to customization. Thus, this finding reflects what is stated in other research, for example from Bol, Høie, Nguyen, and Smit, who stated in their study from 2019 that tailoring received a lot of attention in research over the past decades, while research into customization is still in an early stage. This can be possibly explained by the fact that customization is a rather new concept in behavioural research, as described in the Introduction of this paper.

Four elements were embedded in almost every assessed app. Most apps provided summaries of the individual progress regularly, offered users the opportunity to self-monitor different parameters as for example their current weight or daily calorie intake, adapted the intervention content to the user's needs based on a questionnaire, and asked the user for consent before sending feedback and reminders. The latter element is considered a form of customization, because it provides the user with autonomy by offering him a choice. It can be concluded that certain elements of tailoring and customization that were established in current research are established in practice as well.

## **General Discussion**

The goal of this research was to explore the term customization in two different contexts: current research on behavioural change interventions aimed at physical activity and dietary behaviours and direct-to-consumer diet and fitness mobile phone applications. In order to develop an understanding of customization as a concept in research and practice and to compare both perspectives with each other, two studies were executed.

Study 1 consisted of a systematic literature review on the current state of

customization and similar personalisation approaches in literature, addressing interventions aimed at changing behaviours related to nutrition and physical activity. The main results of Study 1 indicated that customization appears to be a novel, not yet established construct in research. Therefore, it was not yet possible to establish a clear, universal definition of this concept. From the current perspective, customization can be understood as an approach to user adaption which specifies itself by providing users with more autonomy in comparison to other user adaption approaches. Based on these results, a continuum was proposed that situated both tailoring and customization along a range of low to high levels of adaptation to the user. It suggests that tailoring and customization employ user adaptation to different extents and places tailoring in the middle and customization in the upper end of the continuum (Figure 4).

In Study 2 the main goal was to explore the practical application of the concept customization in comparison to the current state of literature that was established in Study 1. To do so, a content analysis of the most popular IOS applications in the "Health and Fitness" category was executed. The results of this analysis indicated an overlap in approaches to user adaptation between research and practice, but only to a limited extent, as not all aspects of user adaption that were established in Study 1 were applied in the direct-to-consumer apps.

In the following discussion a comparison between the current state of literature on customization in eHealth interventions focused on nutrition- and fitness-related behaviours and the application of customization in currently available nutrition- and fitness-focused apps will be drawn. Further, the strengths and limitations of both studies, as well as implications for future work in this direction will be considered.

### **Strengths of this research**

The study design can be considered as a major strength of the current research. The combination of both studies integrates an insight into the current state of research and practice. Through a careful application of the PRISMA guidelines, Study 1 offers a comprehensive overview on the current state of customization and personalisation in behavioural change interventions and therefore offers a reliable basic framework for future research in this direction. Study 2 applied this framework to a coding scheme and therefore transforms the findings of Study 1 into a practical context. It is one of the first tools that attempts to measure tailoring and customization separately from each other. These aspects provide interesting, new insights which could be useful for future research, as literature on customization is still limited. Another aspect which should be mentioned regarding the

strengths of this research is its representativeness. In the two studies, topics of different disciplines are combined by considering traditional behavioural research from psychology and technological aspects from communication science, implementation science, and human-computer interaction. This research offers therefore a multidisciplinary insight into user adaption. As the development of technology-delivered behavioural change interventions requires a combination of knowledge from different fields, adopting a multidisciplinary approach during the development process is important to avoid shortcomings. Research has shown that it makes interventions more effective and user-friendly (Henkemans, van Empelen, Paradies, Looije & Neerincx, 2015).

Finally, the results and conclusions of this study are expected to not only be applicable to interventions focused on nutrition and physical activity but to the whole field of behavioural change interventions in general. The broad range of literature and theories from behavioural research that was taken into consideration to build a basis for this research, makes it possible to consider customization in different contexts too. The coding scheme developed in Study 2 could function as a tool for this.

### **Limitations of this research**

One limitation of this research is the low quality of the integrated literature for Study 1. The studies were of relatively poor quality in some aspects, for example in their consideration of confounders. This might have affected the reliability of the results produced in this research. Integrating literature of higher quality might have led to a different definition of customization in general and possibly to differences in the later developed coding scheme. However, it should be considered that not all included studies are randomized controlled trials, due to the limited availability of these for the current topic, which is a possible explanation for the low results of the integrated studies in the quality assessment.

Another limitation refers to the small number of studies integrated that directly included the term customization, which was the main topic of interest. Only two studies included this term, whereas the other studies that were included used different terms to describe similar techniques for user adaption. Due to the limited number of articles that mentioned customization, we decided to include all studies that described adaptations to or by users in other terms. This has limited the perspective on customization so that it was difficult to establish a unified definition for it from the results of this research. But, this aspect shows that customization is not an established construct across research yet, which supports the conclusion drawn from Study 1.

Considering the limitations of Study 2 it needs to be mentioned that only the free apps were included in the app assessment so that the results might be only generalizable to a certain extent. Assessing fee-based apps as well might have led to different results for the application of customization and tailoring in the apps. Different studies have shown that fee-based apps tend to include more theoretical constructs (Cowan et al., 2012; West et al., 2012). Therefore, it would be expected that apps for which consumers need to pay include more aspects of user adaption in comparison to free apps.

The last limitation concerns the interrater reliability of the coding scheme which was found to be moderate and possibly biases the reliability of the produced results. A possible explanation for this result is the classification of the items describing the different elements of user adaption into tailoring and customization. Although Study 1 established a difference between both approaches, the basic idea is the same for both so that a clear categorisation was found to be difficult for certain items. This implies that a strict distinction between customization and tailoring is not possible.

### **Theoretical Frameworks**

Although only a few of the reviewed studies proposed a theoretical rationale behind their intervention, it was striking that two studies used self-determination theory as a theoretical framework (Patrick & Canevello, 2011; Friederichs, Oenema, Bolman, & Lechner, 2015). The theory, which was introduced in the introduction, refers to the importance of autonomy for successful learning. Both studies indicated that the integration of autonomy in an intervention appears to contribute to the design of a more successful intervention, which implicated that including features that provide autonomy to users into behavioural change interventions. Another theoretical framework which appeared to be relevant for designing interventions in the reviewed articles is the social cognitive theory of Bandura (Phatak et al., 2018; Moutappa et al., 2011; Yoganathan, Duwaraka, Kajanan & Sangaralingam, 2013). Hereby, the results of the intervention indicated that the application of features of the social cognitive theory appears to contribute successfully to designing behavioural change interventions. One relevant feature of this theory for the personalisation of intervention is self-efficacy. It was proposed that a higher self-efficacy makes individuals "more likely to implement effective self-regulatory strategies in adopting and maintaining enhanced physical activity behaviours" (Phatak et al., 2018).

One way to support a higher self-efficacy appears to be the personalisation of interventions. Interventions that present information and content to users that is exclusively

relevant to them and adapted to their needs lead to higher self-efficacy which possibly enhances the success of the intervention (Phatak et al., 2018). Therefore, the assumption can be made that personalisation does not only support autonomy in an intervention but also self-efficacy.

### **Comparison between research and practice**

Despite some overlap in the application of user adaption in research and practice, there are still research-based personalisation and customization elements which are hardly or not at all integrated into practice yet. Such elements were found in all four different categories of the coding scheme. Thus, not one of the categories described in the coding scheme appears to be fully established in direct-to-consumer apps, which supports the assumption of a difference between research and practice.

Another aspect supporting this assumption is related to the results of Study 2. Certain elements were found in the direct-to-consumer apps, but not included in the coding scheme as those were not mentioned in the reviewed literature. Those included for example that apps offered users the possibility to set reminders for a preferred time or topic or the option for users to choose between different metrics to track their data. Therefore, it can be concluded that there are not only aspects from research that are not integrated into practice yet but also vice versa.

Considering this it gets clear that there exists a gap between behavioural research and interventions produced directly for the market. This difference between research and practice might be a possible explanation for the problem described in the introduction, the lack of long-term behavioural change for mHealth interventions developed to improve behaviours related to diet and physical activity, as interventions developed based on findings from research tend to be more effective (Rivera et al., 2016). A possible explanation for this problem could be the huge growth of the eHealth industry during the past years, which has been caused by the rising demand for behavioural health interventions (Vandalotte et al, 2016). This has led to fast developments which were not supported by sufficient research, due to a lack of time. Pagato and Bennet describe this phenomenon in their work from 2013, they propose that the practical developments have "far outpaced research" but also stresses the importance of research being integrated in the development of health technologies again (Pagato & Bennett, 2013). Referring back to the introduction it is striking that not only interventions developed directly for consumers experienced problems with creating a long-term behavioural change, but this problem was also described for interventions developed during research as well (Kwasnicka, Dombrowski, White & Snihotta, 2016; Tsai & Wadden,

2005). A possible explanation for this comes from Glasgow and colleagues, who describe the problems experienced in behavioural research through the fast, technological developments of the past decade. The rapid growth in the eHealth industry has not only influenced the development of interventions for consumers but also created several barriers for research (Glasgow, Phillips & Sanchez, 2014).

Such barriers are related to "representativeness, cost, unintended consequences, impact on health inequities, and sustainability" (Glasgow, Phillips & Sanchez, 2014). This aspect can be linked to the results of Study 1, which showed that customization as a construct cannot be clearly defined from the research perspective yet, although it is applied in practice. The aforementioned issues might be an explanation for this so that customization can be considered as part of the rapid technological developments which make it impossible for research to keep pace with. It can be summarised that there exist differences between research and practice which have been most likely caused by the fast growth of the eHealth industry. This growth has led to barriers for research, by limiting the ability to produce reliable and recent literature, as well as for the development of products for the market, that lack the ability to create sustainable behavioural changes in consumers.

### **Implications for future research**

The first implication for further research is a deeper exploration of customization in the considered context. As shown in Study 1, studies solely focused on customization are rather rare due to the novelty of customization in research. This is in line with the work of other authors, for example, Bol, Hoie, Nguyen & Smit who state in their work from 2019 that "research into customization is still in its nascent stages". Therefore, more research is needed to develop a clear, universal definition of customization as a concept across research. One way to put this into practice is the development of higher quality research on customization, due to the limited availability of such. A larger number of randomized controlled trials assessing the application and effects of customization in behavioural change interventions is needed. Moreover, the current research, especially the previously described continuum, can be used as a starting point for further research in this direction. Also, the findings on autonomy and self-efficacy concerning customization in interventions might be interesting for future research to investigate further. Another implication is related to one of the inclusion criteria for Study 1 which was that a study mentions an approach to user adaption in the intervention that is addressed. This led to the consideration of studies that mentioned any form of user adaption being applied in the included intervention but did not provide further information on how it influenced the outcomes of the intervention. Due to this, only limited conclusions

concerning the effect user adaption had on the interventions can be drawn from this research. Future research should focus on examining the effect of user adaption on interventions to find out how it can be applied to enhance the motivation of users.

A similar implication was given by Morrison and colleagues in their study from 2012, in which they state that future research needs to investigate how and why different design features affect the outcomes of interventions to realise the full potential of eHealth interventions (Morrison, Yardley, Powell & Michie, 2012). To implement this in future research by investigating the effects of user adaption in interventions, the results established in this research can function as an aid to design appropriate interventions as they provide several examples for the application of user adaption in eHealth interventions.

The next implication is that future research should consider developing the results of the current studies further. Applying the coding scheme to a larger sample of apps which also includes fee-based apps, might lead to a broader picture of tailoring and customization in currently available apps. Also, the application of the coding scheme to other types of behavioural change interventions might be an interesting opportunity to gain a deeper insight into the application of user adaption in a different context. This could also be a possible solution to the aforementioned problems regarding the quality of interventions, caused by the gap between research and practice.

The last implication addresses the difference between research and practice as well. Research needs to focus on making the gap between research and practice smaller so that both, literature and products, in the eHealth field can be improved. An important step to do so appears to find ways to adapt research to the fast-growing and changing technological industry (Glasgow, Phillips & Sanchez, 2014). This research makes first attempts in this direction through the development of a coding scheme that is based on insights from current research and applied in a practical context for means of comparison.

### **Implications for Practice**

As mentioned before, current direct-to-consumer interventions experience problems related to the development of long-lasting behavioural changes in their users. This issue needs to be addressed in the development of apps and other health technologies. A reason for those issues seems to be the lack of scientific evidence used for the development of interventions, leading to differences between research and practice (Glasgow, Phillips & Sanchez, 2014). An implication for future developers would be therefore to apply findings of recent research during the development of interventions. This research provides a good example of how

scientific literature and practice can be merged.

Furthermore, the coding scheme developed in this research can be used to improve currently available or newly developed apps with regard to user adaption, by providing various examples for features that could be integrated into an app. The content analysis has shown that there are features applied in research interventions which are hardly or not at all applied in direct-to-consumer apps. Examples for such are, offering users the possibility to modify the user interface or providing users with the possibility to adapt their feedback choosing additional, optional feedback options. Integrating features like these into apps improve the level of user adaption in an intervention, which might enhance the motivation of consumers and lead the developed products to produce more sustainable behavioural changes (Sundar, Bellur & Jia, 2012).

## **Conclusion**

This research provides an overview of the current state of research on approaches to user adaption in behavioural change interventions aimed at physical activity and dietary behaviours, in comparison to its present application in practice. Customization can be defined from the current perspective as a form of user adaption that differs from other approaches through the provision of increased autonomy to users. Further, this research has examined the level of agreement between current research on user adaption and the application of customization and tailoring in currently available direct-to-consumer apps which has shown that a gap between research and practice exists.

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## Appendices

## **Appendix A**

### *Data Extraction Sheet (Raw Version)*

#### Data Extraction Sheet

##### *General Information*

- Date / Year
- Title of Report
- Author
- Publication Type
- Journal
- Aim of Study
- Research Question

##### *Method*

- Study Design
- Intervention
- Number of Participants
- Demographics of Participants
- Duration of Study

##### *Customization*

- Term(s) used to describe customization
- Definition of customization in study context
- Application of customization in study context
- Outcomes related to customization
- Does definition of customization match the chosen definition for this article?

##### *Results*

- Main Outcome
- Strengths
- Limitation
- Conclusion

## **Appendix B**

### *References of studies included in the systematic literature review (Study 1)*

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# Appendix C

## Downs & Black Checklist

Downs, Black

### Appendix

#### Checklist for measuring study quality

##### Reporting

1. Is the hypothesis/aim/objective of the study clearly described?

yes	1
no	0

2. Are the main outcomes to be measured clearly described in the Introduction or Methods section?

If the main outcomes are first mentioned in the Results section, the question should be answered no.

yes	1
no	0

3. Are the characteristics of the patients included in the study clearly described?

In cohort studies and trials, inclusion and/or exclusion criteria should be given. In case-control studies, a case-definition and the source for controls should be given.

yes	1
no	0

4. Are the interventions of interest clearly described?

Treatments and placebo (where relevant) that are to be compared should be clearly described.

yes	1
no	0

5. Are the distributions of principal confounders in each group of subjects to be compared clearly described?

A list of principal confounders is provided.

yes	2
partially	1
no	0

6. Are the main findings of the study clearly described?

Simple outcome data (including denominators and numerators) should be reported for all major findings so that the reader can check the major analyses and conclusions. (This question does not cover statistical tests which are considered below).

yes	1
no	0

7. Does the study provide estimates of the random variability in the data for the main outcomes?

In non normally distributed data the inter-quartile range of results should be reported. In normally distributed data the standard error, standard deviation or confidence intervals should be reported. If the distribution of the data is not described, it must be assumed that the estimates used were appropriate and the question should be answered yes.

yes	1
no	0

8. Have all important adverse events that may be a consequence of the intervention been reported?

This should be answered yes if the study demonstrates that there was a comprehensive attempt to measure adverse events. (A list of possible adverse events is provided).

yes	1
no	0

9. Have the characteristics of patients lost to follow-up been described?

This should be answered yes where there were no losses to follow-up or where losses to follow-up were so small that findings would be unaffected by their inclusion. This should be answered no where a study does not report the number of patients lost to follow-up.

yes	1
no	0

10. Have actual probability values been reported (e.g. 0.035 rather than  $<0.05$ ) for the main outcomes except where the probability value is less than 0.001?

yes	1
no	0

##### External validity

All the following criteria attempt to address the representativeness of the findings of the study and whether they may be generalised to the population from which the study subjects were derived.

11. Were the subjects asked to participate in the study representative of the entire population from which they were recruited?

The study must identify the source population for patients and describe how the patients were selected. Patients would be representative if they comprised the entire source population, an unselected sample of consecutive patients, or a random sample. Random sampling is only feasible where a list of all members of the relevant

population exists. Where a study does not report the proportion of the source population from which the patients are derived, the question should be answered as unable to determine.

yes	1
no	0
unable to determine	0

12. *Were those subjects who were prepared to participate representative of the entire population from which they were recruited?*

The proportion of those asked who agreed should be stated. Validation that the sample was representative would include demonstrating that the distribution of the main confounding factors was the same in the study sample and the source population.

yes	1
no	0
unable to determine	0

13. *Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive?*

For the question to be answered yes the study should demonstrate that the intervention was representative of that in use in the source population. The question should be answered no if, for example, the intervention was undertaken in a specialist centre unrepresentative of the hospitals most of the source population would attend.

yes	1
no	0
unable to determine	0

*Internal validity - bias*

14. *Was an attempt made to blind study subjects to the intervention they have received?*

For studies where the patients would have no way of knowing which intervention they received, this should be answered yes.

yes	1
no	0
unable to determine	0

15. *Was an attempt made to blind those measuring the main outcomes of the intervention?*

yes	1
no	0
unable to determine	0

16. *If any of the results of the study were based on "data dredging", was this made clear?*

Any analyses that had not been planned at the outset of the study should be clearly indicated. If no retrospective unplanned subgroup analyses were reported, then answer yes.

yes	1
no	0
unable to determine	0

17. *In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls?*

Where follow-up was the same for all study patients the answer should be yes. If different lengths of follow-up were adjusted for by, for example, survival analysis the answer should be yes. Studies where differences in follow-up are ignored should be answered no.

yes	1
no	0
unable to determine	0

18. *Were the statistical tests used to assess the main outcomes appropriate?*

The statistical techniques used must be appropriate to the data. For example non-parametric methods should be used for small sample sizes. Where little statistical analysis has been undertaken but where there is no evidence of bias, the question should be answered yes. If the distribution of the data (normal or not) is not described it must be assumed that the estimates used were appropriate and the question should be answered yes.

yes	1
no	0
unable to determine	0

19. *Was compliance with the intervention/s reliable?*

Where there was non compliance with the allocated treatment or where there was contamination of one group, the question should be answered no. For studies where the effect of any misclassification was likely to bias any association to the null, the question should be answered yes.

yes	1
no	0
unable to determine	0

20. *Were the main outcome measures used accurate (valid and reliable)?*

For studies where the outcome measures are clearly described, the question should be answered yes. For studies which refer to other work or that demonstrates the outcome measures are accurate, the question should be answered as yes.

yes	1
no	0
unable to determine	0

*Internal validity - confounding (selection bias)*

21. *Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?*

For example, patients for all comparison groups should be selected from the same hospital. The question should be answered unable to determine for cohort and case-control studies where there is no information concerning the source of patients included in the study.

yes	1
no	0
unable to determine	0

22. *Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time?*

For a study which does not specify the time period over which patients were recruited, the question should be answered as unable to determine.

yes	1
no	0
unable to determine	0

23. *Were study subjects randomised to intervention groups?*

Studies which state that subjects were randomised should be answered yes except where method of randomisation would not ensure random allocation. For example alternate allocation would score no because it is predictable.

yes	1
no	0
unable to determine	0

24. *Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?*

All non-randomised studies should be answered no. If assignment was concealed from patients but not from staff, it should be answered no.

yes	1
no	0
unable to determine	0

25. *Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?*

This question should be answered no for trials if: the main conclusions of the study were based on analyses of treatment rather than intention to treat; the distribution of known confounders in the different treatment groups was not described; or the distribution of known confounders differed between the treatment groups but was not taken into account in the analyses. In non-randomised studies if the effect of the main confounders was not investigated or confounding was demonstrated but no adjustment was made in the final analyses the question should be answered as no.

yes	1
no	0
unable to determine	0

26. *Were losses of patients to follow-up taken into account?*

If the numbers of patients lost to follow-up are not reported, the question should be answered as unable to determine. If the proportion lost to follow-up was too small to affect the main findings, the question should be answered yes.

yes	1
no	0
unable to determine	0

*Power*

27. *Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?*

Sample sizes have been calculated to detect a difference of x% and y%.

	Size of smallest intervention group	
A	<n <sub>1</sub>	0
B	n <sub>1</sub> -n <sub>2</sub>	1
C	n <sub>1</sub> -n <sub>3</sub>	2
D	n <sub>1</sub> -n <sub>4</sub>	3
E	n <sub>1</sub> -n <sub>5</sub>	4
F	n <sub>1</sub> +	5

## Appendix D

**Table 2.**

*Mean scores of quality assessment with the D&B checklist.*

Category	Mean
1. Hypothesis / Aim	1
2. Description outcome measure in methods	0,83
3. Description patient characteristics	0,78
4. Description interventions of interest	1
5. Description distribution of confounders	0,11
6. Description main findings	0,67
7. Random variability estimate provision	0,44
8. Adverse events reporting	0,167
9. Follow-up lost patients characteristics	0,44
10. Reporting of actual probability values	0,44
11. Representativeness requested participants	0,72
12. Representativeness participants	0,78
13. Representativeness of staff & conditions	0,72
14. Blinding of subjects	0,11
15. Blinding of assessors	0,11
16. Data dredging	0,167
17. Minimization of difference for follow-up	0,61
18. Appropriateness of statistical methods	0,72
19. Compliance, absence of contamination	0,61
20. Validity and reliability of outcome measures	0,72
21. Selection of groups from same population	0,72
Recruitment over same period	0,67
Randomization of subjects to groups	0,67
Concealment of randomization	0,5
Adjustment for confounding	0,167
Account of losses to follow-up	0,44
Power	0,61