Analysis of data from alcoholhulp.be and CAD Limburg: Who are the users? Can their characteristics predict adherence?

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Abstract

Introduction
The reduction of alcohol use disorders is one of the most important health targets worldwide. Digital interventions have been widely studied since they are more accessible, anonymous and lack stigmatization and therefore could attract a different user profile. The scope of our study is to investigate the differences in user profile between face-to-face interventions and a web-based intervention and to determine the predictive value of these characteristics for adherence to the intervention.

Method
Data are collected from the web-based intervention alcoholhulp.be and CAD (Centrum voor alcohol - en andere drugproblemen) between January 2016 and June 2019 (CAD patients) /December 2019 (alcoholhulp.be users). Only terminated and alcohol interventions are included with people aged 15-86 years old. Age, gender, education, employment, social status and drinking frequency are compared using descriptive statistics. Regression analyses are used to determine the significance of predictive values of the characteristics for adherence.

Results
CAD patients are mostly male and single/divorced/widow(er), there are more female and married/cohabiting users of the website. The mean age of website users is slightly lower than that of CAD patients. Most users are between 35 and 65 years old in both populations. A higher education diploma and employment is more probable in website users. Twice as many website users tend to drink daily when compared to CAD patients.
For website users neither the socio-demographic characteristics nor the alcohol consumption pattern have a positive predictive value for compliance to the intervention. For CAD, being male is associated with higher adherence.

Conclusion
User characteristics differ significantly between users of the web-based intervention and face-to-face interventions. Adherence among patients in routine specialized care is higher than among users of the web-based program. Male sew is associated with higher adherence but only within the routine specialized care setting. Interventions can be more tailored to individual patient characteristics and that web-based interventions could also possibly be used complementary to face-to-face interventions in order to narrow down the treatment gap of the latter.

Introduction

According to the WHO, harmful use of alcohol is responsible for over 3 million deaths each year, which is 5.3% of all deaths (1). It is also a causal factor in more than 200 disease and injury conditions, making it one of the leading risk factors for population health worldwide (1). More specifically for Belgium, the prevalence of alcohol use disorders (AUD) is estimated at 8.1%, including alcohol abuse and alcohol dependence (2). The reduction of harmful alcohol use thus forms one of the important targets on the 2030 agenda of the WHO (2).

In order to achieve this reduction in harmful alcohol use, brief interventions in primary care are most recommended by guidelines. However, pragmatically, these interventions have a limited effect on the prevalence of harmful alcohol use since few healthcare professionals employ them (3). According to Riper et al., internet-based interventions can fill this treatment gap because of their high accessibility (1), low incremental cost, anonymity, and lack of stigmatization (4,5). Indeed, internet-based interventions are already widely used, and a lot of studies report on their effectiveness to maintain engagement and/or to reduce the amount of harmful alcohol use
In order to optimize this accessibility and thus to reduce the treatment gap, the individuality of each person should be taken into consideration (5). The users of these web-based interventions and their characteristics have been researched by a rather low number of studies. These studies show ambiguous results.
There has also been research investigating whether or not there was a link between user characteristics of participants and outcome. Outcome was defined differently by different authors; some defined it as a reduction of alcohol consumption while others defined it as adherence or attrition rate. According to Gunther Eysenbach's law there are two types of attrition: no usage attrition, which refers to the lack of engagement and dropout attrition, which refers to loss of follow-up (4,6,7). A minimum level of engagement is necessary for the intervention to have its desired effect. Existing evidence about predictive value of characteristics for engagement is ambiguous.

Given that this study is the first to analyze the dataset of this Belgian web-based intervention, we considered it an opportunity to assess the different user characteristics, compare them to known face-to face interventions in Belgium and investigate their predictive value in terms of adherence to the programs. It is important to have knowledge of these characteristics in order to identify who will benefit most effectively from which intervention (5).

Therefore, we addressed the following two research questions. Firstly, how do the user characteristics of the web-based intervention alcoholhulp.be compare to the user characteristics of face-to-face interventions? Secondly, we want to investigate if there are parameters that are able to predict the level of adherence of users of the web-based intervention alcoholhulp.be and users of face to face interventions.

Method

Study design

This study was a retrospective observational study involving an anonymized and automated cross-sectional data collection from the website alcoholhulp.be between 1st of January 2016 and 1st of December 2019. In order to compare these data with those of face-to-face interventions, we also used an anonymized and automated cross-sectional data collection obtained from the CAD (Centrum voor alcohol -en andere drugproblemen) Limburg, a local treatment center for drug and alcohol-related problems, compiled between 1st of January 2016 and 1st of June 2019.

Study sample/participants

From the database of the website alcoholhulp.be, we obtained data from 2682 patients. From the CAD Limburg database, we obtained data from 1092 patients. For the scope of our study only people with an AUD were included. Any other problematic drug uses were excluded.

For both data collections, only patients whose treatment was finished (whether they were compliant or not) and patients between the age of 15 and 85 years old were included. We excluded patients who reported the answer ‘never’ to the question ‘How often do you drink alcohol?’.

Data collection

The website alcoholhulp.be comprehends three different web-based intervention modules. The first is a mostly informative module with a diagnostic test and access to online groups and forums. The second module is an online self-help or unguided intervention. The third module is the one we used for our study; a free guided web-based intervention. In this intervention, users are assisted online by psychologists or psychotherapists for 12 weeks. Enrollment to the latter module requires filling in a short questionnaire regarding sociodemographics and completion of AUDIT-C. The user then sets an alcohol reduction goal and is requested to describe her/his motivation. For 12 weeks, the user keeps a diary and completes exercises that identify risky situations, explore motivations etc. and has access to an online forum. Furthermore, the user participates in a one-on-one weekly chat session with the caregiver in order to discuss recent events, results, difficulties and ask for further guidance. The course of the program, and if needed, further steps to continue therapy, are discussed with the user during a final intervention session at 12 weeks.

CAD is an expertise center that specializes in alcohol -and other drug interventions. We obtained our data collection from the local center situated in the province of Limburg, Belgium. In this center, health care professionals provide ambulatory guidance for people with alcohol -and other drug problems. For the intervention, the health care professionals meet with the users on a regular basis for behavioral therapy. These interventions have no fixed duration. They are ended in agreement with the health care provider and the patient when no further therapy is needed, or on the initiative of the patient alone. The health care providers register sociodemographic factors at the start of the intervention and parameters related to drinking behavior are registered at every meeting.

Sociodemographics

In order to compare the profile of users of the website and CAD, seven parameters that were registered both by alcholhulp.be and CAD were used: age, gender, education, employment status, social situation, frequency of alcohol consumption and the date of registration. Age was subdivided into 3 subcategories (<35 years old, 35-65 years old and >65 years old). Also, education was categorized into 3 categories (‘higher education diploma’, ‘high school diploma’ and ‘no high school diploma’) for there were many subtypes of education registered. Employment status was subdivided into ‘employed’ and ‘non-employed’. Social status was divided into categories ‘single/divorced/widow(er)’ and ‘Married/co-habitant’. Lastly the drinking frequency was subdivided into 5 categories; ‘daily’, ‘weekly’, ‘biweekly’, ‘monthly’, ‘none during the last month’.

Adherence

For the website, adherence to the program was defined as having the program completed, terminated in mutual agreement, terminated by the client and referred (in mutual agreement), and terminated by social worker and referred (in mutual agreement). There was no adherence when the program was disconnected, terminated by client but not referred and terminated by social worker but not referred. For the CAD, adherence to the program was defined as having the program terminated and being referred, terminated in mutual agreement, terminated and referred back to the referrer, terminated by social worker and terminated because of death or suicide. There was no adherence when contact was terminated on the initiative of the client, terminated early, or terminated for other unspecified reasons. Finally, there were some users where the manner in which the program was terminated was not known or not filled in. These were excluded for this research question.

Alcohol consumption

As a measure for alcohol consumption, different scoring systems were used for the website and CAD. The AUDIT-C score was used for the website and subdivided into 3 categories; ‘< 5, 5 - 7, > 7’. We opted for this subdivision because problematic drinking is improbable with an AUDIT-C score less

than 5 for men and less than 4 for women. When the Audit C score is 5 or above, an AUDIT needs to be done. A score of 8 or more indicates hazardous and harmful alcohol use and possible alcohol use disorder. A score of 5 to 7 indicates low hazardous alcohol use (8, 9)
For CAD we used the parameter "severity of the alcohol problem", which is registered by the care providers. We subdivided this parameter into 3 categories 'acceptable' (which included '0-1 not really a problem'), 'problematic' (including '2-3 small problem' and '4-5 serious problem') and 'severe' (including '6-7 severe problem' and '8-9 extreme severe problem').

Data Analysis
Descriptive statistics were used in order to describe the sociodemographic characteristics and drinking behavior of both users of the website and patients of CAD. The parameter age was the only continuous variable and was described by mean values and their standard deviation and categorized into three age ranges that were represented by their absolute values and percentages. Other categorical (education, social status and drinking frequency) and dichotomous variables (sex, employment) were also described by absolute values and percentages.
Pearson's χ^2 test was used to determine whether there were significant differences between the two population profiles and to investigate how patient's characteristics relate to adherence in the programs.
Binary logistic regression was used to assess the relationship between the dependent variables adherence (Age, gender, education, employment status, social situation and score system for alcohol consumption) and the independent variable (adherence). The statistical analyses were performed using Stata 16.

Ethics
Given that our study is a retrospective study of an anonymized database and there was no use of or contact with human material, no approval of the committee of ethics was needed. (ref. MP009504) (See addendum 1)

Results

User profiles
For both populations, users were predominantly between 35 and 65 years old. While almost 25% of the website users were less than 35 years old, this was the case for only ⅕ of CAD patients. For CAD patients, 5% was older than 65 years old, while for website users this was 3% (Chi square, p=0,0007). The mean age for users of the website was 42 (±11,3) years old while for CAD patients it was 45 (±12,3) years old. Website users were mostly female (53,5%), while on the other hand CAD patients were predominantly male (67,9%) (Chi square, p<0,0001). A high school diploma was evident in ⅓ of the website users and in almost half of CAD patients (46,5%). One quarter of the website users had no high school diploma while this was the case in only 15% of CAD patients. For the website users, 36,9% had a higher education diploma, while in CAD patients this was the case in only 22,3% (p<0,00001). Almost 75% of the website users were employed whilst this was the case for less than 60% of CAD patients (Chi square, p<0,0001). More than half of the website users were cohabitant/married while more than half of CAD patients were single/divorced/widow(er) (Chi square, p<0,0001).

Most website users drank alcohol on a daily (72,2%) basis. For CAD patients the drinking frequency was highest daily (36,8%) and weekly (31,0%). 26% of CAD users confirmed not having had a drink during the last month.

Table 1. Sociodemographic -and drinking characteristics of alcoholhulp.be users and CAD patients

Variable	**Alcoholhulp.be users**		**CAD patients**		**p-value**
	N=2684		*N=1092*		
	Absolute value	%	Absolute value	%	
Age					0,0007
<35	644	24,0	225	20,6	
35-65	1961	73,1	811	74,3	
>65	79	2,9	56	5,1	
Sex					<0,0001
Male	1247	46,5	742	67,9	
Female	1437	53,5	350	32,1	
Education					<0,00001
Higher education	990	36,9	244	22,3	
High school diploma	992	37,0	511	46,8	
No High school diploma	671	25,0	167	15,3	
Employment					<0,0001
Yes	1937	72,2	655	60,0	
No	375	14,0	425	38,9	
Social status					<0,0001
Single/divorced/widow(er)	640	23,8	618	56,6	
Co-habitant/Marriage	1573	58,6	467	42,8	
Drinking frequency					
Daily	1938	72,2	402	36,8	
Weekly	490	18,3	338	31,0	
Biweekly	158	5,9	0	0,0	
Monthly	35	1,3	0	0,0	
None during the last month	0	0,0	284	26,0	

Predictors of engagement

Table 2 represents the proportion of users of the website alcoholhulp.be that showed adherence to the program and the proportion of users that quit the program early. In the case of alcoholhulp.be 33,6% of the users were adherent to the program. There were no differences in terms of adherence between the different age categories, gender, education, employment, social situation and audit C scores.

Table 3 represents the proportion of CAD patients that showed adherence to the program and the proportion that quit the program early. For CAD, 46,3% of the users completed the program. Significantly more people of the age above 65 years old showed adherence to the program (7,9%) as compared to younger age-groups (χ^2, p=0,0023). Also, significantly more people who were employed showed adherence to the program (63,5%) compared to those who were not employed (χ^2, p=0,0253) No significant associations were observed between adherence and sex, education, social situation and severity of alcohol use, except for age and employment.

Table 4 and 5 show the results of the binary logistic regression analysis. None of the characteristics of the website users were independent predictors of adherence to the website program (table 4).
Male sex was an independent predictor for adherence to the CAD program (p-value = 0,045; 95% CI [0.585 - 0.994], OR: 0,7629001) (table 5)

Table 2. Characteristics of users that were compliant or non-compliant for alcoholhulp.be

Alcoholhulp.be (N = 2684)					
Variable	**Adherence**		**No adherence**		**P value**
	N= 902 (33,6%)		*N=* 1782 (66,4%)		
	Absolute value	*%*	Absolute value	%	
Age					0,7437
<35	222	24,6	422	23,6	
35-65	662	73,4	1318	74	
>65	18	2	42	2,4	
Sex					0,5622
Male	412	45,7	835	46,9	
Female	490	54,3	947	53,1	
Education					0,5123
Higher education	341	37,8	649	36,4	
High school diploma	334	37	658	36,9	
No High school diploma	213	23,6	458	25,7	
Employment					0,8293
Yes	662	73,4	1275	71,6	
No	126	14.0	249	14	
Social status					0,8481
Single/divorced/widow(er)	225	24,9	412	23,3	
Co-habitant/Marriage	523	58	1050	58,9	
Audit C					0,0928
<5	36	4	49	2,8	
5-7	137	15,2	312	17,5	
>7	689	77,4	1384	77,7	

Table 3. Characteristics of users that were compliant and non-compliant for CAD.

Variable	**Adherence**		**No adherence**		**P value**
	N= 492 (46,3%)		*N = 572 (53,7%)*		
	Absolute value	%	Absolute value	%	
Age					0,0023
<35	103	20,9	111	19,4	
35-65	351	71,2	443	77,5	
>65	38	7,9	18	3,1	
Sex					0,0715
Male	348	70,6	375	65,6	
Female	144	29,2	197	34,4	
Education					0,6564
Higher education	113	22,9	123	21,5	
High school diploma	222	45	275	48,1	
No High school diploma	72	14,6	92	16,1	
Employment					0,0253
Yes	313	63,5	329	57,5	
No	171	34,7	239	41,8	
Social status					0,5838
Single/divorced/widow(er)	274	55,6	329	57,5	
Co-habitant/Marriage	214	43,4	240	42,0	
Alcohol use					0,1889
Acceptable	6	1,33	2	0,3	
Problematic	188	38,1	210	36,7	
Severe	278	56,8	343	60,0	

Table 4. Regression analysis of characteristics predictive for adherence for alcoholhulp.be

Alcoholhulp.be					
Variable	**Odds ratio**	**Std. Err.**	**z**	**P> |Z|**	**95% Confidence interval**
Age	0,94182	0,083113	-0,68	0,497	0,7922308 - 1,119655
Sex	1,043845	0,0858761	0,52	0,602	0,8884001 - 1,226489
Education	0,971545	0,0492861	-0,57	0,569	0,8795931 - 1,07311
Employment	0,9332182	0,0538376	-1,20	0,231	0,8334454 - 1,044935
Social status	0,946234	0,0609317	-0,86	0,391	0,834039 - 1,073521
Audit C	0,85534	0,0683281	-1,58	0,115	0,761151 - 1,119655

Table 5. Regression analysis of characteristics predictive for adherence for CAD

CAD					
Variable	**Odds ratio**	**Std. Err.**	**z**	**P> |Z|**	**95% Confidence interval**
Age	1,172226	0,1547329	1,20	0,229	0,9050097 - 1,518341
Sex	0,7629001	0,1030631	-2,00	0,045	0,5854308 - 0,994168
Education	1,036369	0,066293	-0,56	0,577	0,9142525 - 1,174797
Employment	0,8308832	0,1012381	-1,52	0,128	0,6543743 - 1,055003
Social status	1,048278	0,1293066	0,38	0,702	0,8231509 - 1,334975
Alcohol use	0,9212404	0,1024905	-0,74	0,461	0,7407549 - 1,145701

Discussion

Our study is the first to explore the differences in user profiles of a web-based intervention and a face-to-face intervention in Belgium. We have found a significant difference between the socio-demographic characteristics and alcohol consumption patterns of both populations. While CAD patients were mostly male and single/divorced/widow(er), there were more female and married/cohabiting users of the website. Although the mean age of website users was slightly lower than that of CAD patients, most users were between 35 and 65 years old in both populations. The prevalence of a higher education diploma was significantly higher in website users than CAD patients. Regarding employment, website users were more likely to be employed than CAD patients. Lastly, twice as many website users tended to drink daily when compared to CAD patients.
However, for website users neither the socio-demographic characteristics nor the alcohol consumption pattern have a positive predictive value for compliance to the intervention. For CAD, being male was associated with higher adherence.

Whereas for the website, the population was almost evenly divided by gender in a 1:1 ratio, with a slight predominance of female users, two thirds of the CAD patients were male. Johanssen et al. reported the similar findings in their study of web-based self-help interventions in Sweden (10). This almost equal gender 1:1 ratio for web-based interventions was also reported by Riper et al. in their individual patient data meta-analysis of 19 randomized controlled trials (RCT) (3) and in a RCT of a web-based self-help intervention "Drinking Less" by Riper et al. (11). On the other hand, Garnett et al. reported a majority of male users of both the alcohol reducing app (64.9%) and web-based intervention (61.5%) even though the gender ratio of drinkers in the general population in England was almost 1:1 (12). According to the WHO, the prevalence of AUD in Belgium is three times as high for men (12,1%) as for women (4,3%) (1). Given this, the slight predominance of female website users in our study can suggest a female preference for web-based interventions. This can be explained by fact that web-based interventions may be more attractive for women as they have a greater fear of stigmatization, which comes with face-to-face interventions. (11)
Regarding the relationship status of both populations, more than half of the website users were cohabiting or married, while the majority of CAD patients were single/divorced/widow(er). Riper et al. described in their meta-analysis a similar percentage of website users (58,3%) that had a partner. A possible explanation for this higher number of cohabiting/married website users might also be the stigmatization related to face-to-face interventions and the unwillingness of admitting an alcohol problem and/or therapy to a partner. On the other hand, having a partner also could reflect a lesser impact of AUD on the daily life of users, and therefore also indirectly less harmful drinking. This contradicts however with the drinking frequency of website users described in our study as most users had a daily drinking pattern. Our suggestion for this daily pattern is that users of the website might be in an early stage of AUD.
Furthermore, we can report for both populations that while still being in the same age range of 35 to 65 years old, the mean age of website users (42 years old) was slightly lower than that of CAD patients (45 years old). Riper et al. and Johansson et al. report a similar mean age of respectively 19 web-based interventions users (41,6 years old) and their web-based self-help users (41,9 years old) (3,10). Garnet et al. reported a similar age range (12) for web-based interventions. This suggests that digital interventions engage mostly younger users, since they would be "particularly receptive to digital interventions" and have "higher digital literacy" (13).
When comparing education, almost half of CAD patients had a high school diploma while this was the case in only ⅓ of website users. A higher education diploma though, is more prevalent in website users (37%) than in CAD patients (22%). In their study, Riper et al. reports an even higher percentage (53,8%) of people with a higher education diploma that made use of web-based interventions (3). Some authors explain this by the stigma that more educated people experience for face-to face interventions, while others suggest web-based users require a certain "health literacy", which would be associated with higher education, in order to fully understand the online information (13).
As for employment, almost 75% of the website users were employed, while this was the case in less than 66,6% of CAD patients. Riper et al. also reported an employment degree of 75% in their study (3), while Garnett et al. described that more than 85% of the users of the app 'Drinking Less' were employed. A suggestion for this high employment rate in website users, compared to face-to-face interventions, can be that the website is accessible 24/7 while face-to-face interventions mostly happen during working hours, at a planned time slot. A high employment rate could also suggest, on the other hand, that the problematic use of alcohol has a limited effect on the daily life of users, and that therefore the alcohol consumption must be limited as well. However, when reflecting on the drinking frequency between the two populations, almost twice as many website users drink daily (72%) compared to CAD patients (37%). Unlike this, Davies et al. describe that online tools are mostly used by people with low drinking profiles (13). Our suggestions for these contradictory findings are that website users are possibly at an early stage of therapy, while CAD patients are mostly referred to the center by primary health care providers, possibly with a longer history of AUD.

From our results, we can conclude that there is a higher compliance for CAD than for Alcoholhulp.be. In bivariate analysis, aged over 65 and being employed were significantly associated with adherence to the CAD program, being male was nearly significant associated with adherence. Regression analysis

showed that only sex was a significant independent predictor for adherence. This could perhaps be explained by the fact that the older population consisted more of men.
For the website alcoholhulp.be, none of the user characteristics were predictive for adherence. This is in contrast with what we have found in existing literature. Radtke et al and Linke S et al indicated that being female, older and better educated are predictors for better adherence (4). Also, Bewick et al found out that being female was a predictor for better adherence (6,14, 16) and Postel et al found that age was positively linked with adherence (6,14). Lange et Al. were able to confirm that there was a link between education and adherence in a positive direction (14). On the other hand, other studies did not find a positive correlation between being female (Riper et al), age (Bewick et al) and higher education (Postel et al (6) (14)). Furthermore, some studies suggest that also drinking characteristics tend to have an impact on engagement, but in the opposite direction (4). According to Linke et al and Postel et al, people who consume fewer units of alcohol in a week show lower levels of engagement (4,6). This could not be confirmed in our study as there was no significant difference in compliance between users with a higher or a lower AUDIT C score for both the CAD users and alcohol.be users. Also, Garnett et al were not able to find a correlation between drinking characteristics and engagement (4). According to Andrade Al et al, users with AUDIT score suggesting alcohol dependence or harmful use (AUDIT score >8), showed higher adherence than those with lower AUDIT score (15). On the other hand, Bewick et al claimed that completers used fewer units of alcohol a week and per occasion and showed lower risk of dependency than non-completers (6,17), and Radtke et al was able to conclude that participants with higher AUDIT score were more likely to drop-out from the intervention (15).

One of the major strengths of our study is that it is the first to analyze the data of the website alcoholhulp.be, which is also the only web-based intervention in Belgium. Moreover, the population sample of our study was fairly large and diverse as only a few exclusion criteria were used, while for example most other studies exclude people with low AUDIT scores.
This study also has limitations. While the website alcoholhulp.be is accessible for users throughout the whole of Belgium, CAD is only accessible for patients living in the province of Limburg, a smaller region, but all the same based in Belgium. Also, the period of inclusion of both populations is not quite the same, as for the website this inclusion period was four months longer. However, the overlap of both inclusion periods is rather large. For alcoholhulp.be registrations it was clear whether way of termination of the program could be considered as adherence or not. For a small number of CAD registrations, it was not. Therefore, misclassification could not be ruled out, however the number in which adherence was not clear is small. Lastly, it is important to note that the severity of AUD was assessed and described differently in alcoholhulp.be and CAD. Therefore, only the parameter 'drinking frequency' could be compared between both populations.

Since in our study user profiles differed significantly between both populations, digital interventions could be adapted to certain characteristics in order to be tailored to the individual patient. Nonetheless, the efficacy of digital interventions as a sole intervention is contentious (18). According to Campbell et al. these technology-based interventions 'are most successful when supplemented with occasional therapist support', most beneficially in conjunction with face-to-face therapy (18). Therefore, we suggest that caregivers could implement the website intervention complementary to their face-to-face interventions in order to fill up the treatment gaps left by the latter.
Nonetheless, since in our study we could not find any significant predictive characteristic for adherence to the website program and considering the ambiguous literature, more research is needed. Larger and prospective studies could be carried out to further investigate the outcomes in terms of compliance and engagement. So that treatment, whether face-to-face, through website interventions, or the combination of both, can be adapted to the patient's needs.

In conclusion, users of the web-based program for alcohol-related problems differed importantly from patients attending an outpatient center for alcohol-related problems in terms of demographics and alcohol drinking behavior. Adherence among patients in routine specialized care was higher than among users of the web-based program. Male sew was associated with higher adherence but only

within the routine specialized care setting. For the website alcoholhulp.be we did not intercept any characteristics that could have a predictive value for compliance. The significant difference in demographic and drinking behavior characteristics suggests that interventions can be more tailored to individual patient characteristics and that web-based interventions could also possibly be used complementary to face-to-face interventions in order to narrow down the treatment gap of the latter.

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Addendum 1: Approval ethics committee



KU LEUVEN

SCONE

Geachte professor,
Beste student,

De verstrekte informatie toont aan dat in het kader van uw onderzoek er op geen enkel moment contact zal zijn met proefpersonen of menselijk lichaamsmateriaal. U geeft aan dat uw onderzoek een zuiver retrospectieve studie betreft en dat de reeds beschikbare data enkel niet-identificeerbare persoonsgegevens bevat. Dit betekent dat de data publieke data zijn, volledig anoniem zijn of voorafgaand aan het verwerven geanonimiseerd werden.

Dit type onderzoek vereist geen goedkeuring door een gemachtigde commissie voor medische ethiek.

Onder voorbehoud van de volledigheid en correctheid van de door u verstrekte gegevens, krijgt u hierbij het akkoord om het onderzoek in het kader van de masterproef te starten. Deze mail dient als bewijs van goedkeuring mocht u uw onderzoek wensen te publiceren.

Wij willen u erop attent maken dat u zelf verantwoordelijk blijft voor uw onderzoek. Bovendien doet elke wijziging aan de door u verstrekte gegevens omtrent de onderzoeksopzet deze goedkeuring vervallen. U dient in dat geval een amendement te maken aan uw huidig dossier.

Veel succes!

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