Optimizing **D**elivery of **H**ealth care **IN**terventions
European Union Collaborative Project
WP5 – Cluster RCT
Revised Protocol 4´th of May 2012
Leaders: Fredrik Spak and Preben Bendtsen, Sweden

Participating partners: 2, 6, 7, 8, 9, 10, 11, 12, 16, 18

Participating countries: Spain, Netherlands, United Kingdom, Poland and Sweden

1. Objectives

The aim of WP5 is to study the effect of training & support, financial reimbursement and e-BI singly or in combination, on screening and brief intervention activities in primary health care, compared to treatment as usual. This will be studied in a cluster randomized factorial trial (see **Table 1**).

2. Enrolment of the participating unit

A total of 120 Primary Health Care Units (PHCU) in Catalonia, England, the Netherlands, Poland and Sweden will participate in the study. Each PHCU will be randomized to one of eight conditions (see **Table 1**). In Poland, where primary care physicians work as individual practitioners, a PHCU will be defined for the purposes of the study as a physical location where 3 or more general practitioners work.

In each country, 3 PHCU per allocation group will be recruited giving a total of 24 PHCUs per country. Each PHCU should have an approximate size of 5,000-20,000 registered or listed patients.

Identification of PHCU who agree to participate in the study will be drawn from administrative or academic registries of PHCU at national or regional levels. The process of recruiting PHCU will be described in detail by each country.

3. Inclusion criteria for eligible health care providers

Eligible providers will include any fully trained medical practitioner, nurse or practice assistant with a non-temporary employment contract, working in the PHCU and involved in medical and/or preventive care. At the start of the study, all eligible providers within the PHCU will be identified by the research team. Nonetheless, each eligible provider individually will decide whether to sign up for the study. This will be done during an introduction meeting to the study, before the baseline

measurement, where participating staff will be asked to sign an informed consent for their participation. Staff not able to attend this meeting but willing to participate will be informed by the contact person in the PHCU. These providers will also sign an informed consent for their participation. Providers who change their location will be assessed as drop-outs.

Note: the number of participating providers is not necessarily equal to the number of eligible providers in the practice. This is only allowed if 'eligible' patients (see below) can be calculated for participating providers. If 'eligible' patients can only be calculated for PHCU as a whole, all providers automatically have to sign up for the study as participating providers.

4. Randomization procedure

The PHCU will be the unit of randomization, implementation and measurement. Thus each primary care unit included in the study will constitute a cluster and participating health care providers in the unit will be allocated to the same condition **(Table 1).**

Randomization will take place after formal agreement to take part in the trial (informed consent form, **(Appendix 1**). The PHCU will be randomly allocated to one of eight groups, described below, by the European coordinating centre, using computerized randomization stratifying by country, ensuring 15 provider units per group (3 per country), and randomizing potential PHCU before they start the trial, when enrolment of PHCU are staggered over time. Although the PHCUs will be randomly allocated before the baseline measurement, the research team in each of the countries and the PHCU will only be informed of the allocation after collection of the baseline measurement and formal agreement to participate in the study, to avoid bias as a result of group allocation. For the remainder of the study period, the PHCU and investigators will not be blind to the group allocation.

5. Description of the various conditions/clusters of implementation strategies

1. **Control group, treatment as usual.** The control group will receive a package, either hand delivered or by post, containing a summary card of the national guideline recommendation for screening and brief advice for hazardous and harmful alcohol consumption, without demonstration. In Poland, the summary card will be adapted from the PHEPA guidelines (Gual, Anderson, Segura & Colom 2005) for the purposes of this trial. No further instructions will be given.

2. **Training & support (T&S) group.** In addition to receiving the same package as the control group, the T&S group will be offered an initial 1-2 hours face-to-face educational training, followed by one 10-30 minute telephone support call to the lead PHCU contact person, followed by a second 1-2 hours face-to-face educational training during the twelve week implementation period **(Appendix 2)**. If necessary, one additional face-to-face training of 1-2 hours duration will be offered. The time intervals between the initial training, the telephone call, and the additional optional training will be, on average, two weeks. The training will address knowledge, skills, attitudes, and perceived barriers and facilitators in implementing screening and brief advice, combining theory and practical exercises. The location of the educational training will vary from country to country and include in house meetings at the PHCU or within clusters of PHCUs. The trainers will include peer trainers, members of the research team, accredited teachers or addiction consultants. Each country will use an adapted existing country-based T&S package. In the case of Poland, the T&S package will be based on the PHEPA training programme (Gual, Anderson, Segura & Colom 2005).

3. **Financial incentive group.** In addition to receiving the same package as the control group, the financial incentive group will receive a financial incentive based on both their screening and brief advice activities. They will be paid for the performance within the twelve week implementation period, with a country dependent fee based on normal practices and rates for financial incentives for clinical preventive activities, **see Table 1.**

4. **E-BI group.** In addition to receiving the same package as the control group, the e-BI group will be asked to refer identified at risk patients with an e-leaflet with unique log in codes to an approved e-BI specific package, which will be country specific, or, for Poland based on the WHO e-SBI programme **(Appendix 3).** The website will include the following: Log in facility to allow monitoring of the patient (i.e. patient actually logged-in); suitable brief screening tool with ability to calculate score and give feedback (i.e. brief intervention); appropriate information on sensible drinking guidelines; information on impact of alcohol on health and wellbeing; and a drink diary facility. Furthermore, the website could offer reminder facilities for follow-up activity.

5. **T&S and financial incentive group.** The T&S and financial incentive group will receive the package, T&S and the financial incentives as described above.

6. **T&S and e-BI Group.** The T&S **a**nd e-BI group will receive the package, T&S as above and will be asked to refer identified at risk patients to e-BI as above.

7. **Financial incentive and e-BI group.** The financial incentive and e-BI group will receive the package and will be asked to refer identified at risk patients to e-BI as above. They will be paid for screening, referral performance to e-BI, and brief advice if actually delivered, with the system of pay as above.

8. **T&S, financial incentive and e-BI group.** The T&S, financial incentive and e-BI group will receive the package and T&S as above. They will be asked to refer identified at risk patients to e-BI as above. They will be paid for screening, brief advice activities, and referral performance to e-BI, with the system of pay as above.

6. Study procedure

Preparations

Each participating PHCU will appoint a local ODHIN contact person that is responsible for completing a "process diary" **(see Appendix 4)** provided by the research team. This local contact person will also be the primary person to have contact with the support staff member of the ODHIN research team and should provide practice features, e.g. number of eligible patients. In Poland, the contact person will be all individual GPs participating in the study.

A short, approximately, 30 minutes introductory meeting (*first meeting*) will be held in all PHCU that agree to participate in the study describing the study's purpose, the study design, and data collection

(Appendix 5). At the meeting, eligible staff agreeing to participate will sign an informed consent **(Appendix 1)** and complete a questionnaire on attitudes to alcohol prevention (SAAPPQ questionnaire, **Appendix 6 A**, including also demographic features of the practice and participating providers.

If an interested staff member does not have the possibility to attend the introduction meeting, the contact person of the PHCU will hand out the same written materials as used in the introduction meeting and clarify in short the aim and methodology of the study, before asking for an informed consent to participate **(Appendix 1)**.

Immediately after the introductory meeting, baseline data will be collected during a four-week period.

After the 4 week baseline data collection, all PHCUs will receive a short briefing *(second meeting)* within one month, tailor-made to the arm to which they are allocated. The control group and financial reimbursement only group will just be informed very briefly either by telephone or a face to face meeting reminding them to start using the data collection tally sheets. The financial incentive group will also be explained the reimbursement mechanisms (**Appendix 7).**

Immediately after this short second meeting, the 12 week implementation period of the trial will start with continuous data collection of screening and brief intervention activities. During the last week of the 12 week implementation period the participating staff once again will be asked to complete the SAAPPQ questionnaire. At this time, they will also be asked to give a rough estimate of the average length of an intervention consultation and the average length of a consultation referring to eBI (**Appendix 6 B**).

Then will follow a 6 month period with no contact with the participating PHCU, but each unit will be encouraged to continue doing what we asked them to do for the trial; this implies that it is important to assure that the PHCU have enough e-bi referral cards to last through the this period.

Six months after the end of the 12 week implementation period, the PHCU will be contacted briefly and asked to start a new 4 week registration of screening and brief intervention activities and participating staff will be asked to complete the SAAPPQ one last time during the last week of the follow up. **(Appendix 6 A)**

Screening procedure

Eligible patients for screening will include any patient aged 18+ years who attends a participating provider.

Screening and brief advice will be measured using paper tally sheets, with the exception of Catalonia who will use a computerized tally sheet. The tally sheets include AUDIT-C scores (i.e. identification of at risk patients) with additional boxes to indicate the type of brief advice that was delivered to the patient (at risk). Gender and age of patients will be documented as well as the date of consultation and practice and practitioner name (**Appendix 8**).

Screening can be performed in collaboration with the staff in the reception of PHCU that could hand out the AUDIT-C questionnaire in order for the patient to complete the questionnaire before the

consultation. The PHCU-specific screening procedure should be registered in the process diary by the lead contact person of the PHCU.

During the consultation, participating staff that have signed up to the study will be asked to score the screening instrument to identify screen positives. At risk patients will be defined as those who scored ≥ 5 for men or ≥ 4 for women on AUDIT-C, or who consumed ≥ 280g alcohol per week for men or ≥ 170g alcohol per week for women in Catalonia. Country-specific overview of standard alcohol beverages will be used to determine the unit of alcohol drinks (See section 11 in this document).

Brief intervention procedure

Next, providers will be asked to deliver brief advice of between 5-10 minutes to at-risk patients (see above), to refer to a similar intervention performed by another member of the staff in the health care unit, or to refer to another provider outside the PHCU. A record of what steps are taken will be recorded on the tally sheet prepared for the study (**Appendix 8**). The information could also be collected from electronic medical records as long as all necessary information is retrieved on each individual patient.

For PHCU allocated to e-BI activity, patients, rather than being given direct brief advice by the provider, will be referred to a computerized e-BI programme (which is equivalent to providing brief intervention), using an e-BI referral leaflet. The same tally sheet is used for the e-BI arm as for face-to-face interventions **(Appendix 8).**

Data collection

Data collection of screening and brief intervention activities will be performed during the five measurement periods.

First, during a one month baseline period, *second, third and fourth* during consecutive 4 week periods during the 12 week implementation period and *fifth* during a 4 week follow-up measurement period (during the seventh month after the end of the main implementation period).

During the 4 week baseline measurement period **all participating staff that have signed the informed consent** will be asked to document their alcohol screening and brief intervention activities among eligible patients.

During the 12 week main implementation trial period, **all participating staff that have signed the informed consent** will be asked to screen all eligible patients and to register their alcohol screening and brief intervention activities.

During the 4 week follow-up **all participating staff that have signed the informed consent** will be asked once again to register their alcohol screening and brief intervention activities.

7. Measures

Screening and brief intervention rates

The screening rate will be calculated as the number of patients screened divided by the number of patients eligible for screening (as defined above) per participating provider times 100. The local contact person will provide the number of eligible patients per participating provider to the ODHIN research team.

The brief advice rate will be calculated as the number of at risk patients that either received oral brief advice, were given an advice leaflet, were referred to the e-BI programme, or were referred to another provider in or outside the practice for brief advice, divided by the total number of at risk patients per participating provider times 100. Information will also be collected on the number of screen negatives who received brief advice.

Screening and brief advice rates will be calculated at five time points: the four week baseline measurement period; the three consecutive four week blocks during the twelve week implementation period, and the four week follow-up period during the seventh month after the end of the twelve week implementation period.

Screening and brief advice rates will be calculated at two levels: 1) PHCU-level: at an aggregate level for all participating health care providers in the PHCU who signed the informed consent, and, 2) Provider-level: at an individual level for each participating and actively participating provider. Participating providers will be defined as those who attended the first introduction meeting, or who are identified as joining the study by the local PHCU ODHIN contact person at the first briefing. Actively participating providers will be defined as those participating providers who completed at least 1 tally sheet or computerized record during one of the measurement periods.

Role security and therapeutic commitment

Role security and therapeutic commitment of the participating providers will be measured by the short version of the Alcohol and Alcohol Problems Perception questionnaire, SAAPPQ at 3 time points: at or immediately after the first introduction meeting, at the end of the 12 week implementation period, and during the end of the four week follow-up period. All participating providers who have signed an informed consent will be asked to complete the SAAPPQ at each of the three time points. The responses will be summed within the two scales of role security and therapeutic commitment. Individual missing values for any of the items in a domain will be assigned the mean value of the remaining items of the domain before summation.

In addition to the SAAPPQ, some demographic characteristics of the providers will be measured as well (only baseline).

8. Analyses

Because of the hierarchical structure of the data (individual providers nested within PHCU nested within country) we will perform multilevel analyses of the screening and advice rates to examine the effect of the implementation strategies in comparison with the controls.

The intention to treat analyses will include all participating providers (see above). Per protocol analyses will include only data from *actively* participating providers (see above). In all the analyses we will use exposure to the implementation strategy as co-variate. Exposure will be defined as positive if the providers meet the following criteria: T&S- the provider attended the two face-to-face educational meetings. Financial – the PHCU received the financial incentive; and e-BI – the provider

handed out at least 1 referral card. If these criteria are not met, the exposure will be defined as negative.

Sample size calculation:
It is estimated that 56 PHCU (7 per eight allocation groups) with a minimum of 1,000 eligible patients per month will be needed for a 80% chance of detecting an increase in screening rates from 8% to 12% (ICC = 0.029) and that 120 PHCU (15 per eight allocation groups) will be needed for a 80% chance of detecting an increase in brief advice rates from 4% to 6% (ICC = 0.029) (alpha = 5 %). As country is used as stratification criteria each country have to include a minimum of 24 PHCU. These conservative estimates are based on published evidence of screening and advice rates (Kaner et al 1999; Anderson et al 2004; Funk et al 2005; van Beurden et al 2011).

9. Research fee

In some countries, the PHCU will receive a trial fee. This amount will vary between countries pending on country specific rules and regulations (see **Table 2** and country specific protocols).

10. Timetable

We allow for a flexible start of the various PHCU in each country but the last follow-up should be collected at the latest by the end of December 2013

Final protocol ready	April 2012
All other document (tally sheet, Process diary) ready	April 2012
Local country protocol ready	May 2012
Ethical application in each country	May 2012
Translation of all necessary documents	Sept 2012
WP 5 meeting at the INEBRIA meeting	26 September
Enrollment of PHC units and signing of contracts	April-Dec 2012
Introduction and baseline measurement	Sept 2012-Febr 2013
Start of main 3 month implementation period	Nov 2012- March 2013
Follow up on SBI activity after 6 month	Aug 2013 – Dec 2013

11. Overview of country specific procedures

See table 2 for an overview of country specific procedures

Table 1 Factorial design for 3 interventions: randomization cluster types

Randomisation cluster	"T&S"	Financial incentive	eBI
1	-	-	-
2	+	-	-
3	-	+	-
4	-	-	+
5	+	+	-
6	+	-	+
7	-	+	+
8	+	+	+

Funded by the European Commission's
Seventh Framework Programme
HEALTH.2010.3.1-1: Better understanding of dissemination and implementation strategies.

Table 2. O*verview of country specific procedures*

	Catalonia	**England**	**Netherlands**	**Poland**	**Sweden**
Provider Units	BeveuMenys database filtered for ICS provider units from 5,000-20,000 visited patients per year, existence of computerized alcohol programme, and with no previous training.	NIHR Primary Care Research Network which have not implemented routine SBI programmes	Academic Network of GPs, Nijmegen and Maastricht; Regional primary health care organizations (ROS); Foundation Healthcare centers Eindhoven (SGE)	Centre of Health Care Informatics Systems (CSIOZ) and Pomeranian Medical University database of primary health care provider units filtered for 5,000-10,000 registered patients, 2-3 GP employed and geographical area (north-west, centre, south-east of Poland), without previous training in SBI	Centers in southeast Sweden, including the following counties: Västra Götland, Östergötland and Kalmar
Screening	Department of Health provided computerized instrument to measure alcohol consumption.	AUDIT-C	AUDIT-C	AUDIT-C	AUDIT-C
	≥ 280g alcohol/week men ≥ 170g alcohol/week women	≥5 men ≥4 women	≥5 men ≥4 women	≥5 men ≥4 women	≥5 men ≥4 women
	Computerized	Tally sheets or computerized records	Tally sheets Supplemented with computerized records	Tally sheets	Tally sheets
Intervention	Drink-Less (BeveuMenys)	SIPS materials	National guideline problematic alcohol use by Dutch College of GPs (NHG)	PHEPA guidelines	SPIRA materials and materials from the National Institute of Health
	Computerized	Tally sheets or computerized records	Tally sheets Supplemented with computerized records for identifying eligible patients	Tally sheets	Tally sheets

E-BI	BeveuMenys http://67.199.91.193/	www.DownYour Drink.org modified for ODHIN	www.minderdrinken.nl	WHO adaptation	www.livsstilstest.se/alkohol
T&S	According to the T&S protocol Delivered by research team	According to the T&S protocol Delivered by research team in practices and/or at central meetings	According to the T&S protocol Delivered by hired qualified freelance trainers, trainers from addiction care or trainers of Dutch College of GPs (NHG) to clusters of practices in local areas.	According to the T&S protocol Delivered by research team in practices and/or at central meetings	According to the T&S protocol Delivered by research team
Financial incentive	Maximum of €250 euros per provider, with linear relation to achieved set rates	£1 per completed AUDIT C questionnaire £8 per BA /eBI session delivered	Absolute reimbursement system, €9,- per completed AUDIT-C; €13,50 (equals 1.5 screening consultation) per BA/ e-BI session delivered with maximum (ceiling) of €1250.	€1.25 per completed audit €10 per BA/eBI session delivered	Reimbursement on € 15 per BI delivered and € 15 per e-BI referral. No special fee for screening (included in the research fee). A maximum on €3300 for each provider unit
Research fee	No research fee	To be determined; possibly from NHS service support costs	€250-500 per PHCU	€250 per participating provider	€2800 per PHCU

List of Appendixes

1. Example of informed consent form
2. Overview of training and support criteria
3. Key issues relating to GP facilitated access to internet based brief intervention package
4. Process diary
5. Outline of *first introduction meeting* with PHCU
6. SAAPPQ
7. Outline of *second specific meeting* with the various conditions
8. Tally sheets
9. Checklist for each country – ”what to do”
10. Graphic depiction of the study design.
11. ODHIN WP 5 RCT trial timetable and five possible start-dates

Appendix 1. Example of informed consent form

ID No:

Optimizing Delivery of Health Care Interventions

CONSENT FORM

Please check box

1.	I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions	☐
2.	I understand that my participation is voluntary and that I am free to not participate, without giving any reason	☐
3.	I understand that the GP practice I am attached to will be randomised to one of eight study arms	☐
4.	I agree to comply with the study irrespective of the study arm to which the GP practice is assigned	☐

_____	_____	_____
Name of person giving consent (practitioner)	Date	Signature
_____	_____	_____
Researcher	Signature	Date

Name: Dr/Mr/Mrs/Miss/Ms……..……..……..……

GP practice .....

E-mail address ……..……..……..

Telephone no. (day) …… Mobile phone no ……..……

Appendix 2. Training and Support arm

Rationale

Countries differ largely with regard to usual educational training of primary care staff. It is not possible to draw one satisfactory T&S package that fulfill the specific needs and possibilities of all countries. Therefore, we could argue that the current protocol is a consensus between the needs and possibilities in the countries involved. For reasons of comparison a set of minimal and maximal criteria have been established. Each country has to decide which existing training and support package fits these criteria.

Miranda Laurant, Myrna Keurhorst, Eileen Kaner and Lidia Segura have been involved in the writing of the proposal discussed in June 2011. Partners attending the WP5 meeting June 2011 and two GPs (Paul Cassidy and Jan van Lieshout) gave feedback. The comments have been addressed as far as possible.

This current protocol primarily draws upon the HAZ-report ('Tyne and Wear Health Action Zone') from the UK, a report that contains details of a study which systematically explored with practitioners issues of ideal content (theoretical and practical), acceptability, feasibility and implementability for the Continuing Medical Education sessions (in this report called 'Training & Support').

SBI materials from WHO and also documentation from PHEPA were used. Although, practitioners' needs and views must be taken into account in designing an impactful T&S strategy to improve professional practice. The key thing in the HAZ project was not getting GPs and nurses merely to experience training but also to achieve a process by which the training was actively tried out in practice and reported back on (to see what works, helps, is useable etc). Training sessions address improving knowledge, skills and attitudes by combining theory and practice-based training. This educational character is added by feedback strategies. In the HAZ-report it was agreed to distinct 2 levels of brief intervention: simple structured advice (level 1) and brief behavior change counseling (level 2) which are respectively the content of overall and pragmatic country training sessions. We aim to train essential key aspects of SBI and provide some flexibility considering tailoring procedures to fit with country circumstances.

Example of overall content, which requires a minimum of 3 contact moments (face-to-face + contact/ support by telephone

Part A1: Background and screening principles of hazardous and harmful alcohol:

- Alcohol related-risk and harm
- Evidence for SBI
- Introduction to screening

The first session will provide a didactic background to SBI by covering the following concepts: the standard unit of alcohol; varieties of alcohol-related harm; recommended drinking limits; prevalence of hazardous and harmful drinking etc.; screening and recommended screening instruments (to our

interest it is the most important *that* an effective screening tool is used, instead of *which* effective screening tool is used); description of BI in general; role of SBI in reducing alcohol-related harm; advantages of PHC for SBI delivery; different targets for SBI; evidence on effectiveness; summary of main points. Furthermore, this first session already could be used to give feedback on SBI from baseline performance rates. These rates could be linked and discussed with training staff with respect to SBI rates we expect to achieve with our RCT. This session is delivered by using PowerPoint slides. Trained staff receives a fact sheet of the main points.

Part A2: Simple structured advice: the process of linking screening and brief intervention; the stages of behavioral change model (Prochaska & DiClemente, 1986) and its relationship to BI; an overall care pathway for alcohol; the FRAMES[1] approach (Miller & Sanchez, 1993) for simple brief intervention; and the protocol for delivering simple structured advice based on the brief intervention package. This session is divided by a theoretical part (using PowerPoint) and a practice-based part, by practice-based situations (role-play). Trained staff receive a fact sheet of the main points.

Part B: Feedback and intervision. Practice experiences are discussed: experiences with screening; usage of recommended tools; patient reactions; experiences with delivering brief interventions, perceived barriers and facilitators; which knowledge and which skills need to be optimized and what additional practice tools are needed.

Example of pragmatic, voluntary content

Part C: Brief behaviour change counseling. In the HAZ-report it was experienced that trained staff would need more skills-based training to deliver behaviour change counseling (Level 2 brief intervention). This voluntary session will cover: The cycle of change (Rollnick S., et al. (1999) Health Behaviour Change: A Guide for Practitioners); Disease-illness framework; Introduction to Motivational Interviewing; Gauging patients readiness to change- importance and confidence; assessing motivation. This session is divided by a theoretical part (using PowerPoint) and a practice-based part, by practice-based situations (role-play). Trained staff receive a fact sheet of the main points.

Content Training & Support strategy

The content of the T&S strategy will be based on already existing training packages as used in each country. In other words, we will not develop a whole new training package, although the existing training packages might need some modifications in order to fit the minimal criteria of T&S for reasons of comparison. Each country has to decide which existing training package fits these criteria (see below). Where such training package does not exist (as in the case of Poland), the T&S package will be based on PHEPA training programme.

- [1] structured and personalised Feedback on risk and harm;
- emphasis on the patient's personal Responsibility for change;
- clear Advice to the patient to make a change in drinking;
- a Menu of alternative strategies for making a change in behaviour;
- delivered in an Empathic and non-judgemental fashion;
- an attempt to increase the patient's confidence in being able to change behaviour ("Self-efficacy").

	Minimal requirements	Maximal requirements	Other, none forced criteria
Content Educational training	• Theoretical and practice-based education character. • Training sessions address knowledge, skills, attitudes [1] and perceived barriers and facilitators for implementing SBI ✓ Knowledge (theoretical) - Prevalence of hazardous/harmful alcohol consumption and its consequences (e.g. disease, costs involved, etc.) - Background SBI / relevance of applying SBI activities - Available instruments/ methods for SBI - Protocol for delivering simple structured advice - Stages of behavioural changes (Prochaska & DiClemente, 1986) and its relationship to BI ✓ Skills (role-play/ practice based situations) - The use of screening instruments - Process of linking screening to brief interventions - Brief Intervention methods - FRAMES[2] approach (Miller & Sanchez, 1993) ✓ Attitudes (practice based situations) - Interests in managing	• See minimal requirements • Skills-based training: ✓ Application of cycle of change ✓ Motivational Interviewing	• Existing training package in each country or PHEPA

[2] structured and personalised Feedback on risk and harm;
- emphasis on the patient's personal Responsibility for change;
- clear Advice to the patient to make a change in drinking;
- a Menu of alternative strategies for making a change in behaviour;
- delivered in an Empathic and non-judgemental fashion;
- an attempt to increase the patient's confidence in being able to change behaviour ("Self-efficacy").

	alcohol issues - Open discussion or results of SAAPQ can be used to start up the discussion. • Experiences of a supportive working environment (i.e. availability of necessary tools (e.g. screening instruments, counseling materials), support of peers or other organizations). • Role security/therapeutic commitment (i.e. confidence in SBI; motivated to apply SBI) • Satisfaction (i.e. comfort with SBI)		
Content Support	• Perceived barriers and facilitators ✓ Open discussion of experienced barriers and facilitators ✓ Tips and tricks: how can these barriers be solved? ✓ Peer feedback: sharing lessons & experiences ✓ Trainers: availability of necessary tools and materials • Discussing performance ✓ Sharing experiences how many SBI (if possible, in comparison to each other, and if available with national figures) ✓ Trainer feedback on how SBI is carried out (role play, actual patients)	• See minimal requirements • Discussing performance ✓ on registration rates of screening and brief intervention at baseline and 1 month intervention, in comparison with each other and if available with national figures	

Duration	• 2 face to face moments ✓ 1 hour each • 1 call for support by telephone ✓ 10 minutes	• 3 face to face moments ✓ 2 hour each • 1 call for support by telephone ✓ 30 minutes	
Time schedule	• Week 1: face to face • Week 3: telephone • Week 5: face to face	• Week 1: face to face • Week 3: telephone • Week 5: face to face • Week 7: face to face	
Location			• Within clusters of practices in a local area OR In the practices (in-house meetings) • Clustering based on location of practices (mixed groups for T&S) OR clustering based on intervention groups
Trainers & supporters/ facilitators'			• Qualified trainers: qualification is based on qualification criteria for each country
Availability of materials			• Written or online: ✓ Targeted at patients: Folders/ patient letters or information websites ✓ Targeted at professionals: factsheets/ ✓ reader

Appendix 3

Key issues relating to GP facilitated access to internet based brief intervention package

It is important that this arm of the study is standardised as far as possible and includes the key components across all participating sites. We set out below our recommendations:

1: Each GP should be required to familiarise himself/herself with the chosen internet based brief intervention package. Each should be required to demonstrate evidence of having logged on and spent time reviewing the content.

Competency: Each national centre should develop training and review

2: A printed package should be available to each participating GP to give to each patient receiving the intervention. This should include a printed leaflet/brochure describing the website and giving the URL. It should also state:

- why the practice endorses the website
- why the GP wants the patient to access the website
- how the GP expects the patient to use the website

There is an additional option to use the packs as a mechanism of monitoring GP activity. If each GP is given X packs at the start of the trial, activity could be measured at any stage by counting the number of remaining packs

Competency: Each national centre should produce the packages and distribute them to the practices.

3: Each practice should be supplied with cards including unique 5 digit log-on codes for their patients. The first 2 digits of each log-in code should denote each participating practice (ie 01xxx ; 02xxx etc)

The last 3 digits should denote each patient in the practice who receives the intervention (ie 01001, 01002, 01003 etc)

There is a potential to review patient activity following GP advice, using the unique log-on code to review log-on and access to different parts of the website

If patient and GP agree (with ethics approval) the log-on code could be linked to patient identifier (optional)

Competency : Each national centre should take responsibility for producing and distributing the cards

4: The GPs should spend a minimum amount of time (ideally 2-3 minutes) presenting the pack and the log-on code to each patient. They should explain how they would like the patients to log on to the site and to make the best use of the resources.

Competency: Each national centre should develop training for this

5: The GPs should explicitly state that they will review the patient's experience with the site the next time the patient attends the practice

Competency: Each national centre should develop training for this

Example from the Dutch e-leaflet (translated)

E-leaflet for referral to internet based advice

You just received this referral card from your GP or from another staff member of the primary health care unit. This referral card is handed out because we observed that it is recommendable to reduce your alcohol consumption.

Why this referral?

In The Netherlands about three quarters of the population regularly consumes alcohol. Most of the time alcohol is consumed because it is perceived to create a nice atmosphere, to socialize with, and sometimes people consume alcohol for relaxing, for instance.

Alcohol consumption can easily switch from incidental to habitual consumption or to excessive and harmful drinking. Many harmful alcohol users barely experience negative consequences because of alcohol, or do not relate their physical or mental complaints to their alcohol consumption. Healthcare providers can help to moderate alcohol consumption as well as the internet can. There are some good websites available that can help to moderate your alcohol consumption and are as effective as face-to-face advice from your GP or another staff member.

This e-leaflet will guide you to a website which helps you to monitor and decrease your alcohol consumption. Nonetheless, if you have any questions regarding ways of moderating alcohol consumption or anything else, you can discuss these with your GP or another staff member.

What to do now?

We recommend you to log-on to www.minderdrinken.nl. You can find the username and password in this leaflet. Once you are logged-in you are free to change your user name and password. Your personal information will be regarded as strictly confidential. It is possible to create your personal profile, though you are free to do this.

Your username: 01003

Your password: XXXXX

Scientific study

This internet referral is part of a study that aims to improve prevention of hazardous or harmful alcohol consumption. Your GP participates in this study. The log-in procedure makes us able to count the number of patients that actually logged-in at www.minderdrinken.nl after the referral. Your anonymity is guaranteed and your personal information will not be provided to the research team

Appendix 4

Example on a suggested process diary and checklist

Optimizing **D**elivery of **H**ealth care **IN**terventions
European Union Collaborative Project
WP5 – Cluster RCT

Example of a Process Diary and Checklist to be adapted for each country

PHC unit: …….. Country: ……

Local ODHIN contact person……..

National contact person (NT) of the research team: …….

Process diary and checklist

Activity	Task	To do	When	Responsible (name)
First contact with PHC unit	Schedule time for: - an info meeting - baseline measurement Decide who should be the local contact person at the unit	Contact staff, prepare the introduction meeting Decide data for baseline survey Reserve meeting room		NT (national team)
First meeting	Very short introduction explaining use of tally sheet and study information	NT to LR, LR to staff		LR (Local representa-tive)
Baseline measurement (one moment	Register activity on tally sheets			Participating staff and LR

Report activity result to NT	Send tally sheets		At latest one week after Baseline Check received	LR NT
Second meeting	- Briefing of result randomization, tailor-made to the arm to which they are allocated - National guideline dissemination recommendation for screening and brief advice for hazardous and harmful alcohol consumption among all participating PHCU			NT and LR
SAAPPQ questionnaire	Ask the participants to fill in the questionnaire		Just before the introduction lecture (5 minutes)	NT
Intervention period Intervention period, cont.	-SBI and registering of SBI	Ensure needed instruments are available Participating staff record activity Collect tally-sheets - Mail them to NT Check e-BI program received info	Month before trial During the whole trial During the whole trial Week after trial	LR and NT Participating staff LR LR NT
Following lines are separate for the 8 randomizations cluster groups and give information concerning group specific activities . Please combine the options that are applicable for your PHCU (1-8, see list below).				
TAU: No other procedure than those described above				
T&S				
Activity	Task	To do	When	Responsible
First education	Information		Week 1	NT, LR for logi-tics
	Support		Week 3	NT,

supportive phone call				LR for logis-tics
Second education	Information		Week 5	NT, LR for logis-tics
Financial incentive				
Activity	Task	To do	When	Responsible
Reimburse-ment			Week after trial completion (late spring 2013) Report to NT	LR LR
Reimburse-ment	Reimburse		June 2013	NT
e-SBI				
Activity	Task	To do	When	Responsible
Test	Check e-BI program function		Nov 2012	LR
Test	Check e-BI program function		Week before baseline starts	LR
Follow-up	One month recording of SBI with the same method as used in the intervention phase	- Ensure needed instruments are available - Participating staff record activity - Check that activity is being recorded by staff -Collect tally-sheets - Send tally-sheets to NT - Check that tally-sheets have been delivered	- Week before follow-up month - During the whole follow-up month - During the whole follow-up month - During the whole follow-up month - Week after follow-up period - Two weeks after follow-up period (please observe, dates vary between PCHUs	LR and NT Participating staff LR LR LR NT

Appendix 5.

Outline of the *approximately* 30-45 minute introduction *(first meeting)* to be held before the baseline measurement: Participants at least all eligible staff. In case these cannot attend this meeting must be informed of content by the contact person before start of baseline measurement.

Parts	**Content**	**Estimated time**
1. Introduction of research team and interested professionals		5 minutes
2. Introduction of ODHIN	- objectives of the ODHIN study - design, evidence for BI - implementation research	10 min
4. Tally sheet	- hand out tally sheet with completed example - clarifying the AUDIT-C - clarifying how to register and score	15 min
5. General discussion, response to questions		10 min
6. Signing of informed consent		5 min
7. Completing the SAAPPQ		5 min

Appendix 6 A. The SAAPPQ questionnaire (BASELINE and final follow-up version).

The questions in this section are designed to explore the attitudes of staff working with people with alcohol use disorders. There are no right or wrong answers. Please indicate the extent to which you agree or disagree with the following statements:

1 = Strongly agree
2 = Quite strongly agree
3 = Agree
4 = Neither agree or disagree
5 = Disagree
6 = Quite strongly disagree
7 = Strongly disagree

G ender: ☐ Male ☐ Female
Age: _____ (years of age)
Profession : ☐ GP ☐ Nurse ☐ Practice Assistant ☐ Psychologist ☐ Social worker

		Strongly agree	Quite strongly	Agree	Neither agree or	Disagree	Quite strongly	Strongly disagree
		1	2	3	4	5	6	7
1	I feel I know enough about causes of drinking problems to carry out my role when working with drinkers							
2	I feel I can appropriately advise my patients about drinking and its effects							
3	I feel I do not have much to be proud of when working with drinkers							
4	All in all I am inclined to feel I am a failure with drinkers							
5	I want to work with drinkers							
6	Pessimism is the most realistic attitude to take towards drinkers							
7	I feel I have the right to ask patients questions about their drinking when necessary							
8	I feel that my patients believe I have the right to ask them questions about drinking when necessary							
9	In general, it is rewarding to work with drinkers							
10	In general I like drinkers							

Thank you for taking the time to complete this survey

Appendix 6 b. The SAAPPQ questionnaire (End of 12 week implementation period version)

The questions in this section are designed to explore the attitudes of staff working with people with alcohol use disorders. There are no right or wrong answers. Please indicate the extent to which you agree or disagree with the following statements:

1 = Strongly agree
2 = Quite strongly agree
3 = Agree
4 = Neither agree or disagree
5 = Disagree
6 = Quite strongly disagree
7 = Strongly disagree

G ender: ☐ Male ☐ Female
Age: _____ (years of age)
Profession : ☐ GP ☐ Nurse ☐ Practice Assistant ☐ Psychologist ☐ Social worker

		Strongly agree	Quite strongly	Agree	Neither agree or	Disagree	Quite strongly	Strongly disagree
		1	2	3	4	5	6	7
1	I feel I know enough about causes of drinking problems to carry out my role when working with drinkers							
2	I feel I can appropriately advise my patients about drinking and its effects							
3	I feel I do not have much to be proud of when working with drinkers							
4	All in all I am inclined to feel I am a failure with drinkers							
5	I want to work with drinkers							
6	Pessimism is the most realistic attitude to take towards drinkers							
7	I feel I have the right to ask patients questions about their drinking when necessary							
8	I feel that my patients believe I have the right to ask them questions about drinking when necessary							
9	In general, it is rewarding to work with drinkers							
10	In general I like drinkers							

1. Please estimate the average time per patient you spent delivering brief intervention, excluding time for screening and filling in trial material:_____ minutes/patient

2. Please estimate the average time per patient you spent introducing the e-BI intervention, excluding time for screening and filling in trial material: _____ minutes/patient

Thank you for taking the time to complete this survey

Apppendix 7

Outline of the allocation specific meeting *(second meeting)* to be held before the start of the 12 week implementation period.

Control group:

- Face to face meeting or phone call to PHCU contact person:
    - Informing control groups they can go on with their treatment as usual.
    - Informing a summary card of national guideline will be sent by postal mail
- Contact person is asked to inform the others. Subsequently, all participating staff are informed by letter.
- Research team sends summary card of the national NHG guideline for screening and brief advice for hazardous and harmful alcohol consumption to PHCU, without demonstration

For the interventions groups Research team visits the PHCU and meets with the local contact person and all participating staff. When somebody is unable to attend, he/she must be informed by the local contact person before start of active participation.

Training & Support group:

Research team visits the PHCU and inform all participating staff in a second meeting

- T&S sessions addresses knowledge, skills, attitudes, and perceived barriers and facilitators in implementing screening and brief advice, combining theory and practical exercises
- The PHCU will be offered 2-3 T&S sessions
    - Handout data of T&S sessions
- After first T&S session, the PHCU will be contacted by telephone to receive support from T&S deliverer
- Location of T&S
- Deliverers of T&S
- Informing a summary card of national guideline will be sent by postal mail

- Contact person is asked to inform the others.
-
- Research team sends summary card of the national NHG guideline for screening and brief advice for hazardous and harmful alcohol consumption to PHCU, without demonstration (this will be addressed during T&S sessions)

Financial incentive group:

- Face to face meeting or phone call to PHCU contact person:
    - Explaining the principal of financial incentive- depending on both screening and brief intervention activities (payment after twelve week implementation period)
    - Explaining the value of financial incentives for screening activities and values for brief intervention activities
    - Informing a summary card of national guideline will be sent by postal mail
- Contact person is asked to inform the others.
- Research team sends summary card of the national NHG guideline for screening and brief advice for hazardous and harmful alcohol consumption to PHCU, without demonstration

e-BI group:

- Research team will visit the PHCU and inform all participating staff in a second meeting:
    - Explaining the principal of referring at risk patients with an e-leaflet to the website to be used in the study.
    - Demonstrate e-leaflet to be given to the patients
    - Demonstrate website
        - Log in facility to allow monitoring of the patient (i.e. patient actually log-in)
        - Information about alcohol consumption
        - Facilities of website: baseline alcohol consumption; preparing goals regarding level of alcohol consumption; log of alcohol consumption and setting/ time of consumption; overview of alcohol consumption in time (following log) => follow-up activity
    - Informing a summary card of national guideline will be sent by postal mail
- Contact person is asked to inform the others.

- Research team sends summary card of the national NHG guideline for screening and brief advice for hazardous and harmful alcohol consumption to PHCU, without demonstration

All combinations of strategies, are informed according to the single strategies (see above).

APPENDIX 8 (Example that has to be adapted for each country)

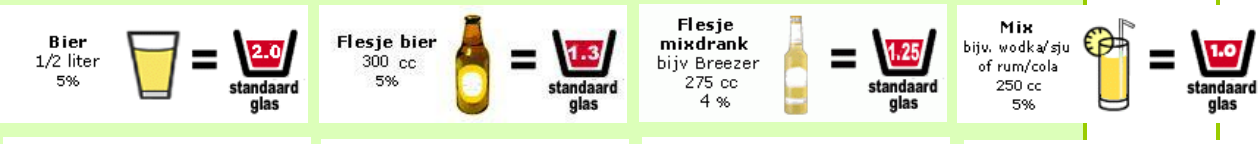
Practice and practitioner name:

.....

Patient details:
Gender: ❑ male
❑ female
Age: ..... years

Date consultation:
.....

AUDIT-C Questions:	Scoring system					Your score:
	0	**1**	**2**	**3**	**4**	
How often do you have a drink containing alcohol?	Never	Monthly or less	2 - 4 times per month	2 - 3 times per week	4+ times per week	
How many units of alcohol do you drink on a typical day when you are drinking?	1 -2	3 - 4	5 - 6	7 – 9	10+	
How often do you have 6 or more units on one occasion?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
Scoring: A total of **5+** for men and **4+** for women indicates increased or higher risk drinking and is therefore AUDIT-C positive.						



Brief intervention: *(Please place a X in following boxes if yes, more than one answer possible)*

- ❑ Oral Brief Advice given, please give a time estimation: ..... minutes
- ❑ Patient Leaflet given
- ❑ e-BI information given to patient
- ❑ Patient referred to other provider in practice for brief intervention
- ❑ Patient referred to other provider outside practice for brief intervention
- ❑ Other .....
- ❑ Time did not allow, but ❑ I made follow-up appointment

- ❑ Patient declined brief advice
- ❑ If offered, patient declined e-BI referral
- ❑ Patient not screen positive, but reinforced about keeping low risk drinking habits

Appendix 9

TO DO

Checklist for each country

What to remember before starting the study.

1. Country specific study protocol ('script')
2. Ethical application including informed consent
3. Translation of all documents, if necessary
4. Going through all logistics concerning data collection
5. Printing of tally sheets in appropriate number (Except Catalonia)
6. Early start of recruitment of PHCU units
7. Going through all legal aspects concering reimbursement
8. Each country is to keep an electronic file of all the final versions of documents that they are to use throughout the trial in their original languages (Tally sheet, SAAPPQ, training material, etc.) and once completed, this file should be sent to the BCN coordinating team for reporting and documentation purposes

Explanation of the graphics used in Appendix 10 on next page

30 min introduction to study (*First meeting*)

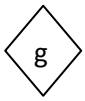
SAAPPQ measurement 1) before baseline; 2) after implementation period; 3) follow-up

collecting tally sheets of SBI activity at 1)baseline; 2)month 1 implementation; 3) month 2 implementation; 4) month 3 implementation; 5) follow-up

15 min *second meeting* introduction to study arms (within control and financial reimbursement only arm- just simple phone call)

Training & Support

Financial reimbursement

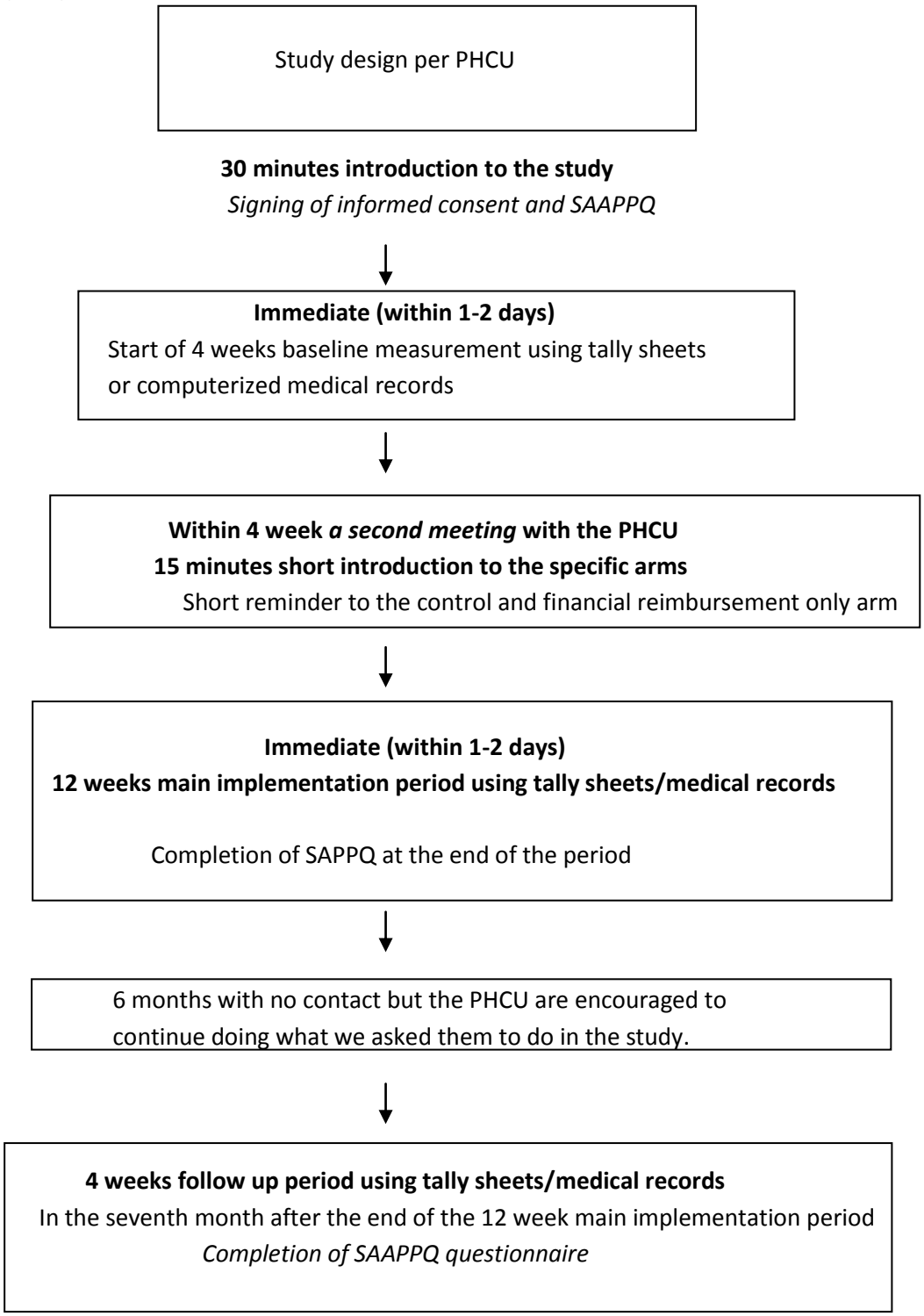


e-BI

Appendix 10 graphic depiction of the study procedures

Timeschedule	***Period***	***Control group***	***T&S***	***Financial***	***e-BI***	***T&S+Fin***	***T&S+e-BI***	***Fin+e-BI***	***T&S+Fin+e-BI***
Baseline: 1 month	*September 2012 – February 2013*	a b c	a b c	a b c	a b c	a b c	a b c	a b c	a b c
Randomisation									
1 month	*October 2012 – March 2013*	d	d	d	d	d	d	d	d
Implementing period : 3 months	*November 2012 – June 2013*	b c	e b c	f b c	g b c	e f b c	e g b c	f b c	e f g b c
Follow-up: 6 months after implementation ended	*July – December 2013*	b c	b c	b c	b c	b c	b c	b c	b c

Appendix 10 (cont)



ODHIN WP 5 RCT trial timetable and five possible start-dates

(all start-dates allow to finish the follow-up measurement in 2013)

Month	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	M13
Activities/ measures	First meeting SAAPPQ 1	Baseline measurement Collecting Tally sheets	Randomization Introduction to arms sessions	Implementation period	Implementation period	Implementation period SAAPPQ 2 including BI time estimation Collecting Tally sheets	Rest period	Rest period	Rest period	Rest period	Rest period	Rest period	Follow-up measure SAAPPQ 3 Collecting Tally sheets
Earliest start	aug. 2012	sep. 2012	oct. 2012	nov. 2012	dec. 2012	jan. 2013	feb. 2013	mar. 2013	apr. 2013	may. 2013	jun. 2013	jul. 2013	aug. 2013
..	sep. 2012	oct. 2012	nov. 2012	dec. 2012	jan. 2013	feb. 2013	mar. 2013	apr. 2013	may. 2013	jun. 2013	jul. 2013	aug. 2013	sep. 2013
..	oct. 2012	nov. 2012	dec. 2012	jan. 2013	feb. 2013	mar. 2013	apr. 2013	may. 2013	jun. 2013	jul. 2013	aug. 2013	sep. 2013	oct. 2013
..	nov. 2012	dec. 2012	jan. 2013	feb. 2013	mar. 2013	apr. 2013	may. 2013	jun. 2013	jul. 2013	aug. 2013	sep. 2013	oct. 2013	nov. 2013
Latest start	dec. 2012	jan. 2013	feb. 2013	mar. 2013	apr. 2013	may. 2013	jun. 2013	jul. 2013	aug. 2013	sep. 2013	oct. 2013	nov. 2013	**dec. 2013**