What to eat and drink for Christmas dinner: a pan-European, observational, cross-sectional study

Running Title: Christmas Dinner: a European Guide

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Abstract

Objective: Digestive discomfort after meals is common in the community at the best of times; however, the problem reaches gut-busting proportions during the festive season. This study assessed the effect of four European Christmas-style dinners with standardized calorie and fat content on self-reported reflux and dyspeptic symptoms. The effect of alcoholic compared to non-alcoholic drinks was also assessed.

Design: Prospective, observational, cross-sectional study

Setting: Hotel restaurant

Participants: 84 clinical academics aged 22-69 years attending a conference.

Main outcome measures: Occurrence of reflux or dyspeptic symptoms. Sensation of fullness and appetite / satiation (100 point visual analogue scale).

Results: Reflux or dyspeptic symptoms were reported by 23% of participants after the low-calorie Czech dinner compared to 30-36% after high-calorie British, German or Italian meals (relative risk compared to Czech meal 1.48 (95%CI: 0.632 to 3.35)). Fat content and alcohol intake had no effect on digestive discomfort. However, in an additional experiment, the increase in fullness and satiation after meals tended to be less marked if alcoholic rather than non-alcoholic beer was taken (fullness +31 vs. +40; p=0.101).

Conclusions: This generally healthy study group tolerated a range of festive food and drink well. The low-fat, low-calorie Czech meal appeared least likely to produce symptoms; however, this was not statistically significant. Alcohol taken before meals may reduce the sense of fullness and satiation after meals. These results allow concerned members of the public to make evidence-based dietary choices at Christmas. The rest of us will continue to eat, drink and be merry!

 Registration: Canton of Zürich Ethics Committee (KEK 2015-0095), ClinicalTrials.gov (NCT02425553)

Introduction

Reflux and dyspepsia are common in the community, with 5-15% of Europeans reporting symptoms such as heartburn, bloating and abdominal pain on a daily basis.(1) Moreover, the problem reaches epidemic, gut-busting proportions during the festive season.

A common belief amongst those lying on the sofa after Christmas dinner is that all this suffering is triggered not by massive overindulgence but rather by certain foods. In Great Britain minced pies, Brussel sprouts, stilton cheese and figgy pudding are often mentioned. In other European countries with different traditions foods such as roast goose, red cabbage, cream desserts and chocolates are blamed. Notwithstanding these claims, no one item has ever been identified as a cause of reflux or dyspepsia in controlled studies. An alternative possibility is that high-intake of certain food groups such as fats, carbohydrates or "biogenic amines" increases the risk of symptoms.(2, 3) Just like all those distended tummies, the debate rumbles on as to whether reflux and dyspepsia are related to general dietary composition or to specific ingredients.

There are inconsistent findings also regarding the effects of alcohol on digestive discomfort. Alcohol contains a lot of calories, slows gastric emptying and increases reflux events after a meal;(4-6) however, moderate intake does not lead to discomfort or decreases appetite.(7, 8) Indeed, drinking alcohol at Christmas seems to go hand in hand with excess consumption.

We performed a prospective, observational study to explore the impact of four European, Christmas-style dinners on digestive symptoms and appetite (satiation) after meals. Each meal contained different ingredients to assess whether specific foodstuffs trigger symptoms, but were standardized for calorie and fat content. In a second study the effects of alcoholic compared to non-alcoholic drinks were evaluated. In both cases clinicians and scientists staying at a conference hotel with an excellent restaurant were studied. This was considered a relevant population because senior clinicians have risk factors for reflux disease being predominantly male, senior in years and with distinguished waist lines.(9, 10) Further, there was no trouble with recruitment, because academics rarely turn down a free meal, let alone a festive feast!

Method

Participants: The Christmas Diners

Faculty and delegates aged >18 years attending a conference 19-24 April 2015 were invited to participate. Individuals with special dietary requirements or clinically significant disease requiring active therapy were excluded.

Participants were given a randomly generated username and password that allowed them to download the SymTrack® mobile application (Gastric Imaging & Analysis, Zürich, Switzerland). No personal identifiers were entered and full anonymity was maintained. The electronic questionnaire was used to enter screening information and document symptoms.

Dietary Intervention: The Christmas Dinners.

Delegates were served a Christmas-style menu and beverages (fruit juice or wine (12% alcohol)) on four consecutive days. Meals were standardized for calorie load and fat content. Table 1 provides nutritional information and Figure 1 displays ingredients. All meals had approximately the same volume and salt content. Completion of the meal and compliance with procedures were documented (i.e. intake of additional food and drink). Participants were not informed of the nutritional content; however, constituents were not disguised and blinding was not complete.

In a separate intervention effects of alcoholic and non-alcoholic beer (both 500ml, ~250kcal) on digestive symptoms were compared. Subjects were randomly served either alcoholic "lager" (5% alcohol) or non-alcoholic "beer" one hour before a high-fat, high-calorie meal. Other procedures were identical.

Outcome measurements

Participants used a 100-point visual analogue scale (VAS) to document symptoms on SymTrack®. The primary outcome was the number of reflux or dyspeptic symptoms during 3 hours after test meals. Secondary outcomes were fullness and appetite (satiation) directly after the meal. The use of an alginate-antacid preparation (Gaviscon Dual Action, Reckitt Benckiser, Slough, UK) as a rescue medication for acute relief of symptoms was also documented.

The study was conducted in compliance with the registered protocol (supplemental material), the Declaration of Helsinki, Good Clinical Practice and all national regulatory requirements.

Statistics

Effects of diet on symptoms were assessed in the following conditions: high fat vs. low fat (calorie controlled), high calorie vs. low calorie (fat controlled), alcohol vs. non-alcoholic beverage (fat and calorie controlled). Analysis of variance (ANOVA) tested for group effects with subject as the random variable and calorie content, fat content and alcohol intake as fixed group variables for between- and within- subject comparisons. For the primary outcome relative risk of symptoms with 95% confidence intervals was calculated. For other comparisons group data was compared by non-parametric tests. p-value <0.05 is significant.

Power calculations indicated that 16 individuals with reflux symptoms are required to provide a 90% chance of detecting a 40% difference in reflux or dyspeptic symptoms (primary outcome)under different conditions.(11) No cross-over effects are expected for dietary interventions performed on separate days.(11) The expected prevalence of patients with reflux symptoms in the study population was 15%,(1) thus, we expected 18/120 conference attendees to report reflux symptoms with the high-fat, high-calorie meals.

Results

For the main study, 70/120 delegates attending the conference consented to participate and completed screening (45 males, 25 females; mean age 46 [range 22 - 69] years; body mass index (BMI) 25 [19 - 34] kg/m^2). At baseline, 17 (24%) participants reported mild and 5 (7%) moderate to severe symptoms on the Leuven Reflux and Dyspepsia Questionnaire (LDQ). Six individuals were taking regular proton pump inhibitors (PPI) or alginate / antacid medications. Three reported upper gastrointestinal surgery. Study progress is detailed in figure 1.

For the second study, 37/100 delegates completed screening and were randomized to alcoholic "lager" or non-alcoholic "beer" (20 male, 17 female; mean age 33 [22 to 55] years; BMI 24 [18 - 32]kg/m^2). 7 (19%) participants reported mild and 4 (10%) moderate to severe symptoms on the LDQ. One individual was taking PPI.

Digestive Discomfort after Christmas Dinners

Reflux or dyspeptic symptoms were reported by 23% of participants after the low-calorie Czech dinner compared to 30-36% after high-calorie British, German or Italian meals (table 2). Overall the relative risk of digestive discomfort after the three high-calorie meals compared to the low-calorie meal was 1.48 (95%CI: 0.632 to 3.35)). Thus, although findings appeared consistent, no significant difference in the risk of symptoms was documented between groups. Fat content and alcohol intake

in the form of wine with the meal (study 1) or beer before the meal (study 2) had no independent effect on the risk of reflux or dyspepsia after the meal (details not shown). The use of Gaviscon to relieve symptoms was reported by 2-4 subjects for all meals.

Fullness and satiation

In the main study only a minority of participants provided both pre- and post-prandial data and this precluded analysis. In the second study, the increase in fullness and satiation appeared to be less marked after ingestion of alcoholic "lager" compared to non-alcoholic "beer" (i.e. after drinking but before dinner). This pattern was maintained after the test meal such that the alcoholic beverage tended to have less effect than the non-alcoholic drink on fullness (+31 vs. +40 VAS; p=0.101) with similar results for appetite /satiation (figure 3).

Discussion

We are delighted to report that no clinical scientists came to harm during this study despite eating Christmas-style dinners on four consecutive days (figure 2)! Indeed, participants not only tolerated, but enjoyed the range of festive food on offer. There was no suggestion that specific ingredients in British, German, Czech or Italian menus caused digestive discomfort. Moreover, there was no robust evidence that the risk of reflux or dyspeptic symptoms was increased after eating high-fat or high-calorie meals; nor did drinking alcohol impact on the sense of wellbeing after dinner.

Picking through the data as one picks through left over food on Boxing Day revealed some tasty morsels of interest. Compared to all three high-calorie meals, the low-calorie fish dinner seemed less likely trigger reflux or dyspepsia (table 2). In each case the relative risk of symptoms was approximately 50% less after this healthy option; however, the 95% confidence intervals crossed unity and the result was not statistically significant. Epidemiological studies suggest that high-fat foods are often consumed by patients with digestive symptoms;(2) however, in real life, it is hard to distinguish the effects of fat and calorie intake. This issue was clarified by clinical research in patients referred for pH-studies that showed the number of reflux symptoms was 40% greater when high-fat, high-calorie rather than low-fat, high-calorie meals were consumed.(11) Carefully controlled studies also show that high-fat meals increase the sensation of fullness and dyspeptic symptoms more than high-carbohydrate meals.(12-14) Taken together, fat intake appears to increase "sensitivity" to reflux events and gastric distention in patients with digestive disease. However, this effect could not be confirmed in the generally healthy group of individuals taking part in our study.

Alcohol has complex effects on digestive function and eating behaviour. Physiological research, including our seminal work on "what to drink with a Swiss cheese fondue",(6) has shown that alcohol slows gastric emptying and increases reflux events.(4-6) However, consistent with population-based surveys,(7, 8) this study provided no evidence that alcohol triggers reflux or dyspeptic symptoms. Indeed, there was some suggestion that taking 500ml beer before meals did not increase the sensation of fullness or suppress appetite (figure 3). This adds to evidence that alcohol makes it easier and more rewarding to eat more than one should,(15, 16) leading to "passive over-consumption" by up to 30% energy intake.(17, 18) These effects could explain late-night trips to the fridge to satisfy "the munchies" and will come as no surprise to anyone contemplating their figure after a boozy Christmas holiday.

This study assessed the impact of diet and alcohol on digestive sensations in a "real life" situation. This was feasible in a relatively large group of subjects because a fixed menu was provided by the hotel restaurant and symptoms were documented using a mobile app without interrupting dinner table conversation. The main weakness of the study is that, although sufficient participants with digestive symptoms were recruited, statistical power was sub-optimal because of inconsistent participation on test days (figure 1) and variable compliance with procedures… not surprising given the happy distractions of conference life and the availability of free alcohol! Future studies must learn from this experience because clarifying the link between food and drink and symptoms such as reflux and dyspepsia is important. Positive findings will help to explain the cause of disease and identify novel treatment strategies. Negative findings will allay unnecessary concerns about food allergy and intolerance that are very common in patients and that impact on the quality of life in general and enjoyment of Christmas in particular.(3, 19)

In conclusion, these results allow concerned members of the public to make evidence-based dietary choices at Christmas. The rest of us will continue to eat, drink and be merry!

Acknowledgements:

Declarations

Details of contributors: Helen Parker developed the study protocol, monitored study procedures and submitted the manuscript. Henriette Heinrich, Michael Sauter and Michael Hollenstein consented participants and performed study procedures. Jelena Curcic designed the mobile application used to monitor digestive symptoms and analyzed the data. Werner Schwizer and Edoardo Savarino contributed to the study and reviewed the manuscript. Mark Fox wrote the protocol, supervised study procedures and drafted the manuscript. Werner Schwizer was investigator sponsor and is guarantor for the study. All authors had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis.

Table 1

Nutritional data for test meals on test days 1-4 (figure 1 displays ingredients). The cross-over study design was partially balanced for calorie and fat content. A fully balanced design was not possible as a realistic high-fat, low-calorie Christmas dinner does not exist! The effect of alcohol was compared against equicaloric fruit juice as a control for the high calorie, high fat meal condition (day 1 and 4).

1. British (HFHC):   High calorie (1200 kcal), High fat (50% energy), 400 ml juice (230 kcal)

2. German (LFHC):   High calorie (1200 kcal), Low fat (20% energy), 400 ml juice (230 kcal)

3. Czech (LFHC):   Low Calorie (600 kcal), Low fat (20% energy), 400 ml juice (230 kcal)

4. Italian (HFHC):   High calorie (1200 kcal), High fat (50% energy),

   300 ml wine (40 g alcohol, 230 kcal), 100 ml water

Table 2

Absolute frequency and relative risk of reflux and dyspeptic symptoms compared to the low-fat, low-calorie Czech Christmas dinner are provided. For comparison, the frequency of symptoms reported by subjects in the Praha "beer vs. "lager" study are also shown.

	# subjects (total =70)	# subjects with reflux or dyspeptic symptoms	%	Relative Risk (95% CI)
Day1 British (HFHC)	47	11	23%	1.32 (0.492 - 3.57)
Day2 Germany (LFHC)	60	16	26%	1.57 (0.626 - 3.97)
Day3 Czech (LFLC)	48	9	18%	1.0 (control)
Day4 Italian (HFHC + wine)	34	9	26%	1.56 (0.545 – 4.47)
	# subjects (total =37)	# subjects with symptoms	%	
Summer School (HFHC + "lager" 5% alcohol)	19	2	10%	
Summer School (HFHC + non-alcoholic "beer")	18	5	23%	

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Figure Legend

Figure 1

Christmas dinners: a pan-European guide. Main courses not as presented in the restaurant.

Day 1: British turkey breast with bacon, mashed potatoes and Brussel sprouts followed by fruit pudding (high-fat, high-calorie with fruit juice). Day 2: German smoked pork loin with boiled potatoes, red cabbage and chestnuts followed by chocolate mousse (low-fat, high-calorie with juice). Day 3: Czech baked fish with rice and mixed vegetables followed by fruit salad (low-fat, low-calorie with juice). Day 4: Italian beef (osso bucco) with saffron risotto followed by strawberry tiramisu (high-fat, high-calorie with wine). See table 2 for nutritional data.

Figure 2

Study progress and participation in the prospective, observational study of diet on digestive symptoms.

Figure 3

A 500ml drink of non-alcoholic "beer" increased gastric fullness and satiation from baseline values. In contrast, alcoholic "lager" had minimal effect on either sensation. Note that final sensations were similar in both groups after the meal was completed.

Figures

Figure 1

Day 1: British

Day 2: German
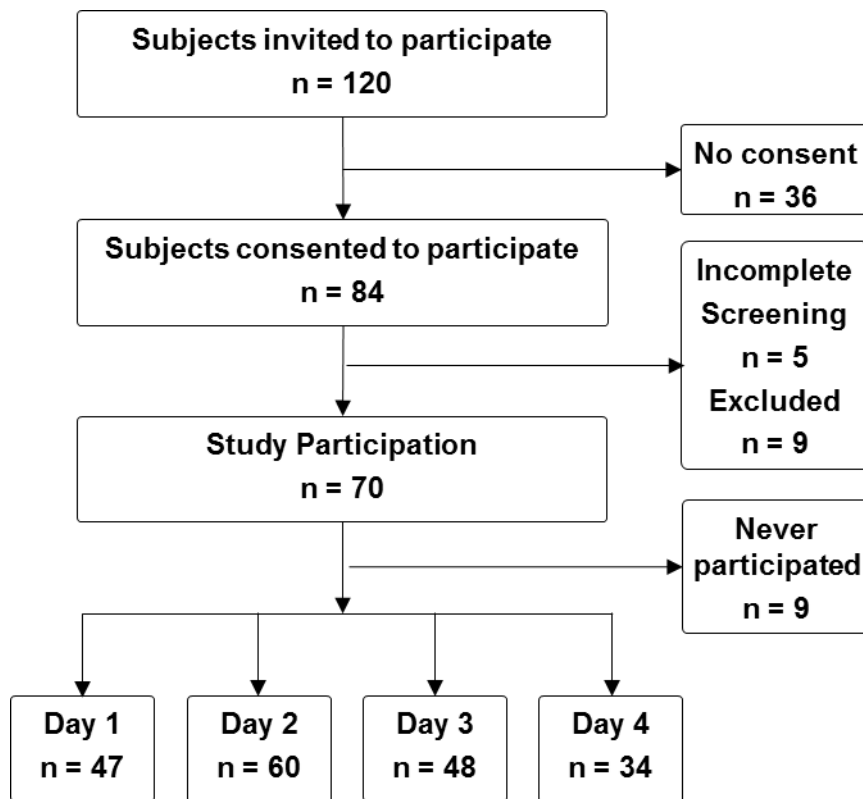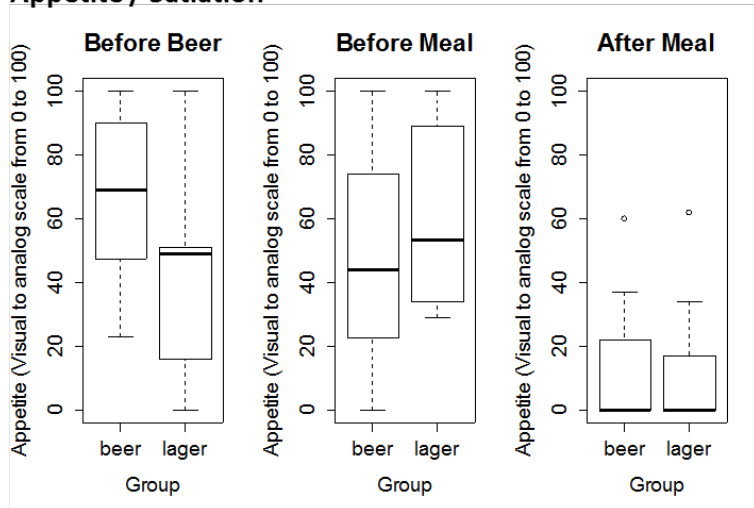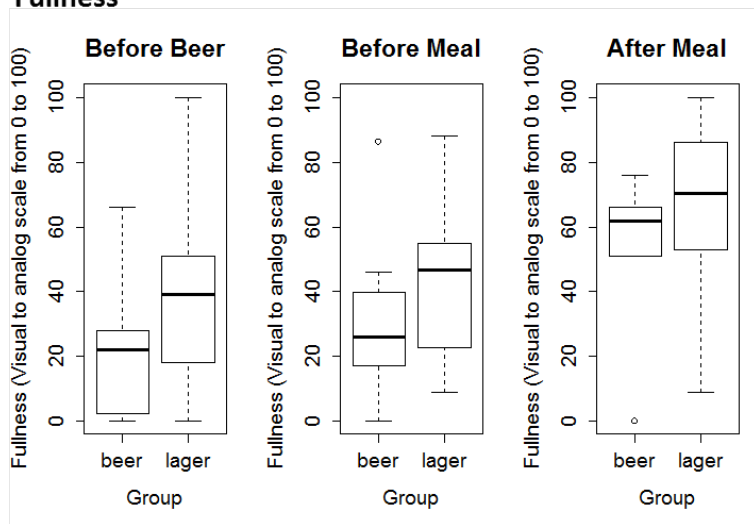

Day 3: Czech

Day 4: Italian

Figure 2

Figure 3

A 500ml drink of non-alcoholic "beer" increased gastric fullness and satiation from baseline values; whereas, alcoholic "lager" had minimal effect on either sensation. Sensations were similar after the meal was completed.

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Appendix

Symptom Tracker

makes your research more efficient and more fun!

If you are planning a research study where the participants regularly have to answer questions or enter specific values about their symptoms or sensations, Symptom Tracker will make your life much easier.

Symptom Tracker is a new smartphone application designed for research studies. However, Symptom Tracker is more than just an app. It comes with everything you need to conduct your research study electronically. With Symptom Tracker, the study participants can enter all data directly into their smart-phones. Notifications can even be used to remind participants to enter their symptoms.

All the participant's data is sent immediately to the server where it is securely stored in your database. Our secure administration website enables you to safely login and monitor the data in real time. All of your data is available for you to download at any time.

The advantages:
► Increase participant compliance: The participants will follow your study protocol more reliably thanks to the reminder function.

► Reduce study processing time and costs: Hours of staff time and costs are reduced as there is no need for the tedious work of collecting and scanning paper symptom diaries.
► Reduce the likelihood of errors in your data: There is no need for potentially error-prone digitalisation or manual data entry. Instead, all your data is ready for download with just one click.
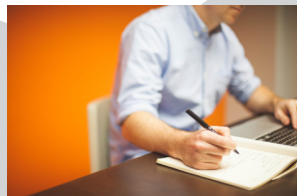
Let us convince you in the following pages, that Symptom Tracker will make your research indeed more efficient and more fun!

How Can You Use Symptom Tracker in Your Study?

Get an idea of how you can incorporate Symptom Tracker in your study with the following three-step process.

Step 1: Design your Study

How many participants do you intend to include in your study? What symptoms would you like them to record? Are there any additional questions you want them to answer, for instance age, weight and height for screening purposes? How often do you want them to receive a notification on their smart-phone as a reminder?

Quickly implement your study design via the administration website. The Symptom Tracker app automatically adapts to reflect your study design and presents your questions to the participants. We are glad to assist you with ethics approval by providing you with a technical description of Symptom Tracker.

Step 2: Start your Study
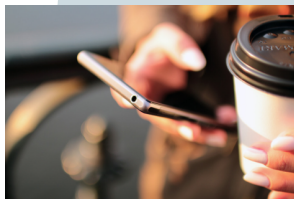
Provide each participant with a personal username and password, for instance during the informed consent process. Your participant can instantly download the app, login and start entering symptoms.

All data entered by the participants via smart-phone is sent to the server. At all times you can monitor the progress of the study and have a quick glimpse at the data entered so far. The monitoring feature enables you to recognize if a participant does not conform to the study protocol. This gives you the advantage to intervene as soon as possible.

Step 3: Analyse your Data

At all times, you can download your database as a CSV-File (comma separated values), which allows for an easy import into Microsoft Excel, Matlab, R, SPSS or any other tool for statistical analysis.

This feature enables you to perform a preliminary analysis part way through the study, which will give you an idea of whether to continue recruiting or not.

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What Can You Do With Symptom Tracker?

Explore the possibilities of Symptom Tracker and how it can be tailored to suit your exact needs.

Flexible Design

Thanks to our modular and flexible design, Symptom Tracker can be quickly customized to your specific needs. The Symptom Tracker mobile application is available as a free download to your participants in the App Store and the Google Play Store. By specifying your study setup via the Symptom Tracker administration website, you can instantly adjust the appearance and function of the app. You provide your participants with a personal username and password, they download the app and log in to your specific study.

Your Study Setup

As the study coordinator, you are specifying the study setup. The study setup consists of the so called Symptom Groups, the Questions and the Reminder Schedule.

The Symptom Groups

By grouping your questions into several Symptom Groups, you can arrange your questions logically and clearly. For each Symptom Group, you can specify a visible title. Decide
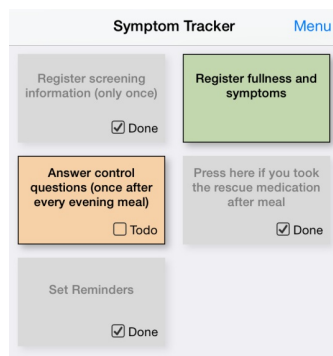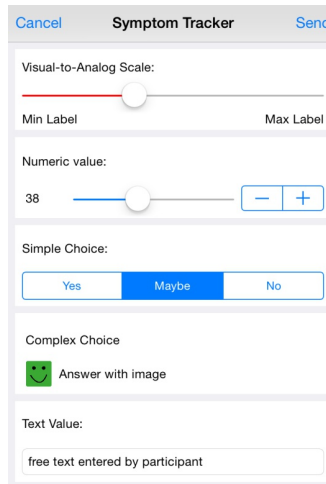

Figure 1: Symptom Groups

Figure 2: Symptom Types

if the participants have to enter the corresponding questions just once or repeatedly. Symptom Tracker visually illustrates this by marking a Symptom Group as "to do" or "done", respectively (cf. fig. 1). As the participant selects one of the Symptom Groups, the corresponding questions appear.

The Question Types

For each Symptom Group, you can define any number of different questions. Each question can be of one of the following question types:
► Visual-to-Analog-Scale (a moving slider with a customized minimum and maximum label)
► Numeric value (a number inside customized limits)
► Simple Choice (few short answers, e.g. yes, maybe and no)
► Complex Choice (many long answers, with images, e.g. the 7 choices of the Bristol Stool Scale).
► Free text input

See figure 2 for examples and try it out for yourself with our demo account.

The Reminder Schedule

Symptom Tracker comes with a notification system, which reminds the participants to register the symptoms according to your study protocol. During the study design, you can define, when the participants should register their symptoms. Just once? Every 3h

The Ascona Diet Study

In April 2015, Symptom Tracker made its first appearance during a congress held in Ascona, Switzerland.

The congress participants (faculty and visitors) were asked to participate in the study designed by the researchers from University Hospital Zurich, Switzerland.
For 4 days, 80 participants were tracking their fullness and reflux and dyspeptic symptoms during and after each evening meal. With the data gathered in this study, the researchers investigated the impact of the meals' calorie and fat content on these symptoms.
Symptom Tracker made it feasible to register symptoms of all participants during their evening meals.

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during day-time (but not during the night)? Once a day for a month? Twice a day, once on 08:00 in the morning, once on 17:30 in the evening? Anything is possible. You can define your reminder times as absolute values (e.g. on 2nd February, 2016 at 08:00 CEST) as well as relative values (e.g. 24h after the participant sets the reminders).

The Participants' Logins

You can have as many participants as you like. Just create a new participant by entering an arbitrary username and password, and instantly, these credentials can be used to login to the Symptom Tracker App! For larger studies, you can even upload a list of usernames and thereby create hundreds of accounts within seconds.

The Administration Website

As the study coordinator, you get access to our administration website. Via the administration website, you are in full control of your study setup. Amongst other things, you can:
- ► Change the study setup (add, remove and change symptom groups and questions)
- ► Change the schedule (add, remove and change notifications)
- ► Add and remove the participant's logins (usernames and passwords)
- ► View and download the study data tracked by your participants

Is Symptom Tracker secure?

Since patients and healthy subjects enter sensitive personal data into Symptom Tracker, information security is one of our main concerns. Typically, a local ethics committee also demands a certain security standard for any IT system used in a research study. This is why we secure all data transfer between the participant's smart-phone and our server with the Transport Layer Security protocol (TLS) using a certificate issued by the SwissSign AG certification authority. Additionally, we recommend all our clients use anonymized login details, i.e. login details which do not give any indication as to the identity of the participant. A master-key-file or study identification log should be kept somewhere secure in case unblinding or separate identification of participants is necessary.

Are you interested? Please contact us for a free test-run with your specific study setup!

Try out our demo!

- ► Download the Symptom Tracker App from the App Store (iPhone) or the Google Play Store (Android Phone). Search for SymTrack.
- ► For Windows Phones, open your mobile browser instead and visit symtrack.gastric.ch.

Log in with the demonstration account:
- ► Username: demo
- ► Password: 1234
- ► Study-ID: demo

Contact us at info@gastric.ch. We are glad to provide you with a demo account for our administration website and give you any further details. Please request our current price list.

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