RESEARCH ARTICLE

Do north-eastern German pharmacies recommend a necessary medical consultation for acute diarrhoea? Magnitude and determinants using a simulated patient approach [version 1; peer review: 1 approved, 2 approved with reservations]

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Abstract

Background: To determine if pharmacy staff in Germany referred patients to a medical consultation for a scenario in which consulting a doctor was mandatory ('appropriate outcome') and what the quality of questioning and – if a medication was dispensed – the quality of information provided were in this context. Moreover, to determine which factors predicted a necessary referral to a doctor.

Methods: A cross-sectional covert simulated patient study was conducted in a random sample of community pharmacies stratified by location in the German state of Mecklenburg-Vorpommern. Each pharmacy was visited once by one of four trained investigators. They simulated a symptom-based request involving a grandmother with acute diarrhoea. A multivariate binary logistic regression analysis using potential variables from bivariate analysis was carried out to determine the predictors for a referral to a doctor.

Results: All 199 planned visits were conducted. A necessary referral to a doctor was recommended in 59.8% (n=119) of all test purchases. Multivariate analysis revealed that a non-pharmacist as opposed to a pharmacist and two or more questions as opposed to no questions were significantly associated with a referral to a doctor.

Conclusions: Regarding the necessary referral to a doctor, an enormous potential for improvement was revealed for community pharmacies in the German state of Mecklenburg-Vorpommern. The results should make both the Mecklenburg-Vorpommern pharmacy association and legislators aware of the need to significantly escalate their quality management efforts.

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Any reports and responses or comments on the article can be found at the end of the article.

Keywords

Non-prescription drugs, Community pharmacies, Consultation, Patient simulation, Diarrhoea, Germany

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Introduction

Acute diarrhoea is one of the most common diseases worldwide¹, including in Germany². While worldwide about 1 billion people develop acute diarrhoea each year², causing about 2 billion cases of acute diarrhoea³, about 30% of the German population suffer from acute diarrhoea episodes each year². Because those affected report becoming ill on average 1.7 times per year², this means that about 42 million cases of acute diarrhoea can therefore be expected in Germany.

According to the guidelines of the German Society of General Medicine and Family Medicine, acute diarrhoea is an imbalance between secretion and absorption in the bowels, whereby the symptoms last fewer than 14 days and are associated with an increased frequency ($\geq$ three loose stools in a day) or an increased water content ($\geq$ 75%) or an increased stool weight ($\geq$ 250 g)⁴.

Acute diarrhoea may be a result of infections with viruses (for example, noroviruses or rotaviruses), bacteria (for example, non-typhoidal Salmonella or diarrheagenic Escherichia coli) or parasites (for example, Cryptosporidium parvum)⁵. More than 90% of cases result from infections, with viral infections being the most common cause⁶. Bacterial infections on the other hand are more often associated with travel, food poisoning and comorbidities. Medications (e.g. antibiotics, cytostatics, diuretics), gastroenterologic disorders (e.g. ulcerative colitis, Crohn's disease), endocrine disorders (e.g. hyperthyroidism, adrenocortical insufficiency) or other medical conditions (e.g. amyloidosis) can also trigger acute diarrhoea⁵.

In Germany there is no medical consultation in about two-thirds of cases of acute diarrhoea². Therefore, advice should be provided by the pharmacy, not least because of the wide range of possible causes, when the diarrhoea is self-medicated with over-the-counter (OTC) medications only available from pharmacies in Germany. As part of a high quality consultation, pharmacy staff should also identify when it is necessary to refer a patient to a medical consultation based on the symptoms^{7,8}. In Germany, in addition to pharmacists, pharmacy technicians and pharmaceutical technical assistants are also permitted to advise on and sell medications but only under the supervision of pharmacists.

Although studies available from Germany regarding the quality of advice provided in pharmacies reveal significant deficits, analogous to the international literature^{9–12}, indications other than acute diarrhoea in adults are usually investigated in scientific^{13,14} and non-scientific studies^{15–19}. The quality of advice provided for acute diarrhoea in adults was analysed for Germany for the first time in 2014 and also identified clear deficiencies²⁰. Despite performance feedback used in the process, a follow-up study identical to that conducted in 2014 was carried out for the first time in Germany in 2017 and also showed poor quality of advice^{21,22}. All the above mentioned studies have in common that they are based on the simulated patient (SP) method to determine the quality of advice provided. In this method test persons simulate participation in an apparently real service provision process to subsequently evaluate the process and reveal any deficiencies as a result²³.

In the baseline study in 2014 (as well as the follow-up study in 2017) the four scenarios investigated were designed as 'moderate' in that none of the scenarios predicted referral to a medical consultation by the pharmacy staff as an 'appropriate outcome'. Both studies also investigated only the quality of advice in 21 pharmacies in a medium-sized northern German city (a total of 84 test purchases for each study).

The aim of this study was, therefore, to determine on the basis of a considerably larger number of pharmacies whether the pharmacy staff referred patients to a medical consultation for a scenario in which consulting a doctor was mandatory ('appropriate outcome') and what the quality of questioning and – if a medication was dispensed – the quality of information provided were in this context. Factors influencing the 'appropriate outcome' were also determined analogous to other national and international studies^{14,21,24–27}.

Methods

Design

A cross-sectional study design was chosen in accordance with the 'STROBE Statement – Checklist of items that should be included in reports of cross-sectional studies'²⁸ and, to determine the quality of advice provided in the pharmacies investigated, based on the highly recommended²⁹ SP method that is often used internationally^{23,30–33} as a form of participatory observation³⁴.

Setting and participation

Because of time constraints of the SPs, the test purchases took place over winter between 1 November and 15 December 2018 in the German state of Mecklenburg-Vorpommern (31 December 2017: approx. 1.61 million residents, 23,214 km² area, low population density of 69.4 residents/km²)³⁵. Upon request by telephone, the Pharmacy Association of Mecklenburg-Vorpommern did not want to provide a list of all registered community pharmacies in the state. Consequently, these pharmacies were identified using the pharmacy finder of the website Apotheken-Umschau.de³⁶. All community pharmacies that had a postcode in the state of Mecklenburg-Vorpommern on the reference date of 1 October 2018 using the postcode search of the pharmacy finder were included in the study. These hits were validated with a corresponding Google search. As a result, a basic population of $N=396$ pharmacies was determined. A comparison with the last available information from the German Federal Chamber of Pharmacies (ABDA) for the end of 2018 regarding the total number of pharmacies in Mecklenburg-Vorpommern³⁷ showed a 99% agreement. The minimum necessary sample size (n) was determined for a population size (N) of 396 and an error margin (e) of 0.05 using the following formula, which is based on a degree of variability of $P=0.5$ and a 95% confidence interval³⁸:

$$n = \frac{N}{1 + N(e)^2} = \frac{396}{1 + 396(0.05)^2} = \frac{396}{1.99} = 198.99$$

In Germany there are no studies yet on a necessary referral to a doctor for acute diarrhoea by community pharmacies. Therefore, the degree of variability is unknown. The assumed degree

of variability of $P=0.5$ maximises the required sample size. The 396 pharmacies were stratified by location of the pharmacy as an indicator for urban/rural and assigned a random number using the MS Excel random number generator and then a simple random sampling was performed in each stratum to select the 199 participating pharmacies.

Scenario and assessment

The Ordinance on the Operation of Pharmacies in Germany includes an obligation for pharmacies to introduce a quality management system. The aim is to ensure a preferably adequate advice outcome³⁹. To ensure that this can be achieved, the Federal Chamber of Pharmacies has drafted various guidelines and tools, including the tool 'Information and advice as part of self-medication using the example of self-diagnosis of diarrhoea'⁴⁰. This forms the basis of the symptom-based test scenario developed (Table 1) and the evaluation form used (see the assessment items in Table 4). The recommendation to consult a doctor by pharmacy staff is defined as the appropriate outcome and the test scenario was also designed according to this. Diarrhoea being present for five days as well as a high fever (40°C) are both considered to exceed the limits of self-medication according to the tool. The evaluation form includes a total of eleven items with the first six items evaluating whether appropriate questions were asked. On this basis the pharmacy staff should then decide whether to recommend that the patient consult a doctor (item seven). Because the tool also considers 'dispensing a medication in an appropriate quantity up to referring to a doctor' within the discretionary powers of the pharmacy staff, also in the case of the limits of self-medication being exceeded and the necessary referral to consult a doctor, items eight to eleven evaluate whether a medication was dispensed and whether in the process information on the dosage, duration and side effects was provided.

Only objective items were used in order to avoid a subjective assessment and thus latitude in the evaluation by the SPs (for example, on the friendliness of the pharmacy staff). Therefore, to complete the individual items only dichotomous scales were used (closed yes/no questions). To avoid the Hawthorne effect⁴¹ and to ensure a realistic consultation situation, the test purchases took place without first informing the pharmacies included in the random sample in accordance with other national^{20,21} and international^{26,42,43} studies.

Data collection

As part of their three-semester research project at the Neubrandenburg University of Applied Sciences, two female and two male Masters students in the Health Sciences faculty, that is, four SPs, were available for the test purchases. Each pharmacy was visited once (a total of 199 test purchases), whereby the pharmacies were distributed randomly across the four SPs (three SPs 50 test purchases, one SP 49 test purchases).

Before the start of the data collection, each of the SPs familiarised themselves with the theoretical principles of the methodology and the contents of the evaluation form.

A pilot study with four test purchases was then carried out by each of the SPs to train the SPs in the use of the methodology and to verify the functionality of the collection form and the four test scenarios. The total 16 test purchases were carried out in pharmacies that were not part of the stratified random sample. No changes to the test scenarios and the collection form were required after testing the scenarios.

The test purchases were carried out on different days of the week and at different times of the day. The SPs made their request to the pharmacy staff who first approached them. The SPs only provided additional information if they were then asked by the pharmacy staff to ensure that the information provided is invariable.

Along with the items on the evaluation form, the SPs planned, analogous to the international literature (Table 2), to also collect a number of variables before, during and after the test purchases that may possibly affect the appropriate outcome.

The particular evaluation form was completed immediately after the test purchases by the SPs to minimise any recall bias of the study results due to faulty memories.

Data analysis

Data were entered in duplicate into and analysed with SPSS software (IBM, Armonk, NY, USA), version 25 for Windows. As part of the descriptive statistics, frequencies and percentages were determined. Furthermore, 95% confidence intervals (CI) for categorical data using bootstrapping methods were also

Table 1. Test scenario.

Scenario
The simulated patient (SP) enters the pharmacy and asks for a medication for diarrhoea. The SP does not have a particular product in mind.
When questioned by the pharmacist, the following information is provided:
- Preparation is for the 75-year-old grandmother   - Diarrhoea present for five days   - Not known how often the symptoms occur   - Fever (40°C) since this morning; no vomiting; not known whether blood in the stool   - No medical consultation to date   - Existing medical conditions: Diabetes and high blood pressure; not known what medications are taken regularly

Table 2. Possible influencing factors and time and type of data collection.

Possible influencing factors	Time of data collection	Type of data collection
Location of the pharmacy ¹⁴ as indicator for urban/rural	Before the test purchase because stratification variable	Precise measurement by allocating the number of pharmacies identified to the particular location
Pharmacy quality certificate ²⁴	After the test purchase	Precise measurement using a telephone query by the SP after completing the test purchase
Age of the pharmacy staff ²⁶	During the test purchase	Estimate using visual impression of the SP
Gender of the pharmacy staff ²⁶	During the test purchase	Exact measurement using visual impression of the SP
Professional group of the pharmacy staff ²⁷	During and after the test purchase	Exact measurement based on the name tag, the receipt and, if necessary, using a telephone query by the SP after completing the test purchase
Queue – patients waiting after the SP ⁴⁴	During the test purchase	Exact measurement using visual impression of the SP
Time of the test purchase ²⁵	During the test purchase	Exact measurement using the SP's watch
Number of questions asked ²⁵	After the test purchase	Exact measurement by adding up the individual questions asked

Note: The possible influencing factors are taken from the particular literature sources.

reported. Because the rule of thumb for sample size assumptions (minimum of 10 events per predictor variable) is given for a logistical regression⁴⁵, a binary logistic regression model was developed to identify the influence of various independent variables (Table 2) on the appropriate outcome. All independent variables were checked for outliers and multicollinearity. According to Hosmer *et al.*⁴⁶, variables with a P value less than 0.25 in the bivariate analysis were included in the multivariate analysis. Crude odds ratios (COR) and adjusted odds ratios (AOR), 95% confidence intervals (CI) and P values were reported. A P value less than 0.05 was deemed significant in multivariate analysis.

Ethical approval

The study protocol was approved by the institutional ethics committee of the Neubrandenburg University of Applied Sciences (registration number: HSNB/GPM/139/18). According to the 'Guideline for the use of mystery research in market and social research'⁴⁷, the data collected were anonymised and recorded in such a way that the pharmacies involved could not be identified. Because of the nature of this study, pharmacies were not asked for consent to participate. Recruited students provided their written informed consent to act as SPs.

Results

All 199 planned test purchases were actually carried out, with a total of €784.70 used from the primary author's own resources. Table 3 shows the socio-demographic data for the 199 pharmacies and the advising pharmacy staff.

This reveals that the pharmacies are mostly in locations with competing pharmacies nearby. In addition, only a minority of the pharmacies had a quality certificate. In most of the test purchases, the advising pharmacy staff were female, between 30 and 49 years of age and did not have a pharmacy degree (non-pharmacist).

The appropriate outcome was achieved in 59.8% (n=119) of all test purchases (Table 4). Most commonly the question 'for whom is the medication?' was asked (75.4%, n=150), while 'clarification by a doctor' was asked the least (17.6%, n=35). In 87.9% (n=175) of all test purchases a medication was dispensed. Regarding the test purchases in which a medication was dispensed, in 88.6% (n=155) information was provided about the dosage of the medication whereas information about possible side effects was only provided by the pharmacy staff in 8.0% (n=14) of test purchases.

The binary logistic regression model is shown in Table 5. Bivariate analysis demonstrated that only three (quality certificate, professional group of the pharmacy staff, number of questions asked) of eight predictor variables having a P value < 0.25 were included in a multivariate logistic regression model.

In this multivariate analysis, being a non-pharmacist (AOR = 2.446; 95% CI = 1.025–5.835; p = 0.044) or pharmacy staff with an undetermined professional group (AOR = 3.269; 95% CI = 1.208–8.843; p = 0.020) as opposed to a pharmacist and two (AOR = 15.291; 95% CI = 4.876–47.955; p < 0.001) or three or more (AOR = 23.406; 95% CI = 8.204–66.773; p < 0.001) questions as opposed to no questioning were significantly associated with referral to a doctor. The location of the pharmacy, the presence of a quality certificate and a queue, the age and the gender of the pharmacy staff, as well as the time of day of the test purchases did not have any significant effect on the appropriate outcome. The model returned a Nagelkerke R² value of 0.45.

Discussion

Although the appropriate outcome, that is, the recommendation to consult a doctor, was achieved in approximately 60% of all test purchases, approximately 40% of all pharmacies did not

Table 3. Socio-demographic data for the pharmacies or the advising pharmacy staff.

	Frequency (n)	Percentage (%)
All pharmacies	199	100
Location of the pharmacy		
• 1 pharmacy in the location	37	18.6
• 2–4 pharmacies in the location	58	29.1
• 5–19 pharmacies in the location	45	22.6
• ≥ 20 pharmacies in the location	59	29.7
Pharmacy quality certificate		
• No	125	62.8
• Yes	52	26.1
• Not able to be determined	22	11.1
Age of the pharmacy staff		
• < 30	39	19.6
• 30–49	110	55.3
• ≥ 50	50	25.1
Gender of the pharmacy staff		
• Male	20	10.1
• Female	179	89.9
Professional group of the pharmacy staff		
• Pharmacist	54	27.1
• Non-pharmacist	90	45.2
• Not able to be determined	55	27.6

Table 4. Assessment items (n = 199).

	Yes		
	Frequency (n)	Percentage (%)	95% CI
1. For whom is the medication?	150	75.4	69.3–81.4
2. How long have the symptoms been present?	97	48.7	42.2–55.8
3. How often do the symptoms occur?	46	23.1	17.6–29.1
4. Have other symptoms occurred?	56	28.1	22.1–34.7
5. Have the symptoms already been clarified by a doctor?	35	17.6	12.6–23.1
6. Are there other medical conditions or which medications are taken regularly?	65	32.7	26.1–39.2
7. Is a medical consultation recommended (appropriate outcome)?	119	59.8	53.3–66.3
8. Dispensing of a medication	175	87.9	83.4–92.5
9. Information about dosage	155	88.6	83.4–93.1
10. Information about duration	82	46.9	39.4–54.3
11. Information about side effects	14	8.0	4.0–12.6

recommend that the patient consult a doctor even though this would have been necessary. Due to the design of the scenario as a symptom-based query, the study results obtained would probably be worse in everyday consultations with its mix of symptom- and product-based queries because in the international and national literature (otherwise identical) scenarios

showed a better quality of advice for a symptom-based query than for a medication-based query^{20,48}. In another study a recommendation rate for a necessary medical consultation of 57% was determined for a medication-based query, likewise for acute diarrhoea in adults, in Australian community pharmacies²⁷. Considerably worse results for the recommendation of a necessary

Table 5. Possible factors influencing the recommendation of a necessary medical consultation.

Possible influencing factors and categories	Total n = 199 n (%)	Referral n = 119 n (%)	No referral n = 80 n (%)	COR (95% CI)	P value	AOR (95% CI)	P value
Location of the pharmacy							
• 1 pharmacy in the location	37 (18.6)	24 (20.2)	13 (16.3)	1			
• 2–4 pharmacies in the location	58 (29.1)	33 (27.7)	25 (31.3)	0.715 (0.305–1.676)	0.440		
• 5–19 pharmacies in the location	45 (22.6)	27 (22.7)	18 (22.5)	0.813 (0.330–2.000)	0.651		
• ≥ 20 pharmacies in the location	59 (29.7)	35 (29.4)	24 (30.0)	0.790 (0.337–1.851)	0.587		
Pharmacy quality certificate							
• No	125 (62.8)	70 (58.8)	55 (68.8)	1			
• Yes	52 (26.1)	35 (29.4)	17 (21.3)	1.618 (0.821–3.188)	0.165		
• Not able to be determined	22 (11.1)	14 (11.8)	8 (10.0)	1.375 (0.538–3.512)	0.506		
Age of the pharmacy staff							
• < 30	39 (19.6)	21 (17.6)	18 (22.5)	1			
• 30–49	110 (55.3)	66 (55.5)	44 (55.0)	1.286 (0.616–2.684)	0.503		
• ≥ 50	50 (25.1)	32 (26.9)	18 (22.5)	1.524 (0.649–3.580)	0.334		
Gender of the pharmacy staff							
• Male	20 (10.0)	10 (8.4)	10 (12.5)	1			
• Female	179 (89.9)	109 (91.6)	70 (87.5)	1.557 (0.617–3.933)	0.349		
Professional group of the pharmacy staff							
• Pharmacist	54 (27.1)	25 (21.0)	29 (36.3)	1		1	
• Non-pharmacist	90 (45.2)	54 (45.4)	36 (45.0)	1.740 (0.880–3.439)	0.111	2.446 (1.025–5.835)	0.044*
• Not able to be determined	55 (27.6)	40 (33.6)	15 (18.8)	3.093 (1.391–6.877)	0.006	3.269 (1.208–8.843)	0.020*
Time of the test purchase							
• 8:00 am – 12:00 pm	77 (38.7)	48 (40.3)	29 (36.3)	1			
• 12:01 pm – 4:00 pm	89 (44.7)	49 (41.2)	40 (50.0)	0.740 (0.397–1.379)	0.343		
• 4:01 pm – 8:00 pm	33 (16.6)	22 (18.5)	11 (13.8)	1.208 (0.512–2.850)	0.666		
Queue							
• No	146 (73.4)	86 (72.3)	60 (75.0)	1			
• Yes	53 (26.6)	33 (27.7)	20 (25.0)	1.151 (0.603–2.196)	0.669		
Number of questions asked							
• None	36 (18.1)	7 (5.9)	29 (36.3)	1		1	
• one	39 (19.6)	10 (8.4)	29 (36.3)	1.429 (0.478–4.268)	0.523		
• two	41 (20.6)	32 (26.9)	9 (11.3)	14.730 (4.863–44.616)	< 0.001	15.291 (4.876–47.955)	<0.001*
• ≥ three	83 (41.7)	70 (58.8)	13 (16.3)	22.308 (8.079–61.597)	< 0.001	23.406 (8.204–66.773)	<0.001*

Abbreviations: COR = Crude Odds Ratio; AOR = Adjusted Odds Ratio.

* significant at P < 0.05.

medical consultation are seen in the international literature for other indications such as pain (recommendation rate: approx. 27%⁴³), vaginal thrush (recommendation rates: 10% and 22%⁴⁹) and asthma (recommendation rates: 40% and 19%⁵⁰) which were all medication-based queries. In contrast, the only study that has investigated the recommendation for a necessary medical consultation to date in Germany showed a very high recommendation rate of 90% once again for a medication-based query for an antacid¹³.

Possible reasons discussed in the international literature for the poor quality of advice provided include lack of time, manpower, interest and knowledge on behalf of the pharmacy staff^{10,48,51,52}. In regards to the lack of knowledge, as part of the pharmacy degree (pharmacist) or professional training (pharmaceutical technical assistant) patient consultations should be more intensively trained using examples⁴⁴. In addition, the systematic use of checklists could also help to ensure a better quality of advice in daily patient contact⁵³.

On the other hand, the international literature reveals that pharmacy staff most definitely have the knowledge to provide good advice, but it is only inadequately applied in actual patient contact^{51,54–56}.

In a German study, pharmacy staff suggested that this is due to the worry that the client may feel patronised¹³. In contrast to this, another German study determined that most patients would like to have a consultation in the pharmacy; however, due to the study design this involved rather health-conscious and therefore not representative study participants⁵⁷. In a very recent German study it was stated by pharmacy staff that patients frequently did not want any advice in terms of drug handling, sometimes due to a lack of time⁵⁸. In a somewhat older English study, 62.5% of the patients interviewed did not expect to be asked any questions by the pharmacy staff during their last purchase of a non-prescription medication⁵⁹. Similar results were obtained in a more recent study in Qatar in which the pharmacist cited ‘no interest by the patients’ as the central reason for providing insufficient advice⁴². Another very recent qualitative study from Australia was also able to determine in this context that from the perspective of both the consumers and the pharmacy staff, the frequent lack of privacy is also an important reason for the poor exchange of information⁶⁰. It would, therefore, be necessary to require pharmacy owners in future to provide appropriate spaces that ensure privacy.

Analogous to other international studies^{50,61,62}, the number of questions asked had a significant effect on the appropriate outcome. This is based on the rationale that the right decision – in our case to recommend consulting a doctor – can only be made if appropriate questions are asked and thus information is obtained about the patient. In contrast to this, a Saudi Arabian study revealed that there was no relationship between the number of questions asked and the appropriate outcome – in this case the dispensing of prescription medications without a medical prescription²⁵. However, the outcome ‘dispensing prescription medications without a medical prescription’ is not comparable to the outcome ‘recommendation

to consult a doctor’. While for the first a sensible decision can be made even without asking appropriate questions (that is, refusing to dispense a prescription medication without a corresponding medical prescription), for the latter a sensible decision is only possible on the basis of appropriately asked questions.

In regards to individual questions, the question about the duration of the acute diarrhoea was asked more frequently compared to comparable national studies^{20,21}. In a recent SP study, also for acute diarrhoea in adults, that was conducted in Iraq, this question was asked in almost 80% of all test purchases⁶³. Considerably worse, on the other hand, are the results of a comparable Turkish SP study, which also investigated the quality of advice provided for acute diarrhoea in adults, in which this question was only asked in 26% of all test purchases⁶⁴. Because certain medications can cause diarrhoea, the question about any pre-existing medical conditions or the patient’s medical history is particularly important⁶⁵. This question was asked in this study in approximately one-third of the test purchases and is thus more frequent than in the comparable national studies^{20,21}. In the similar Turkish SP study, this question was not asked in a single test purchase⁶⁴.

Depending on the particular criteria being investigated, there are also clear differences in the information that is given to the patients when medication is dispensed. Analogous to the national^{20,21} and international literature^{54,66}, information is often provided about the dosage of the medication but rarely about possible side effects. An active query by patients could help to greatly improve the frequency of advice provided for the criterion ‘side effects’, as was shown in a recent SP study from Tanzania⁶⁷.

Along with the number of questions asked, the professional group of the pharmacy staff providing the advice also had a significant influence on the appropriate outcome. Non-pharmacists (pharmaceutical technical assistants and pharmacy technicians) have a significantly higher likelihood of achieving the appropriate outcome than pharmacists. On the other hand, two comparable SP studies from Germany and Australia – also for acute diarrhoea in adults – did not show any significant difference in the quality of advice provided by the two professional groups²¹ or a significantly higher likelihood for pharmacists²⁷ of achieving the appropriate outcome. In the Turkish SP study pharmacists made significantly more recommendations to their patients than pharmaceutical technical assistants⁶⁴. For indications other than acute diarrhoea in adults there was an analogous picture – either a significantly better quality of advice provided by pharmacists compared to non-pharmacists^{14,62} or no significant differences between the two professional groups^{48,54,68}. Due to inconsistent national and international studies and in light of the surprising results obtained in this study, future studies should investigate in greater depth this influencing factor for the advice provided.

Strengths and limitations

This is the first German study that investigated to what degree community pharmacies recommend a necessary medical consultation for acute diarrhoea in adults. The sample size used

in the study (n=199) is also considerably larger than the international median sample size (n=112) for SP studies⁶⁹. An SP study design also avoids social desirability, unlike a survey. By using 4 SPs, the study also satisfies the requirement of not having fewer than 2 (generalisable) but also not too many (standardisable) SPs⁶⁹.

By way of qualification, it must be stated that the results only refer to one scenario. In addition, only one indication was investigated.

Because the study results only refer to one German state, future studies should be expanded to include additional or all German states.

The results also refer only to a quite specific time because the study is a cross-sectional study. There is further need for research to determine whether and, if yes, how the results change over time, which is only possible with a longitudinal study design.

The audio recordings recommended in the literature for quality assurance⁷⁰ must be omitted for data privacy reasons because all pharmacies would have to be informed about this in advance, which would jeopardise the covert study design. Although the particular evaluation forms were filled out by the SPs immediately after visiting the pharmacies and only objective evaluation criteria were used, recall bias²⁶ and the intra- and inter-observer variabilities typical for SP studies⁷¹ cannot be completely ruled out. For greater quality assurance, future SP studies could always carry out and evaluate test purchases in parallel using two persons (1 SP and 1 observer)⁷².

Although in the literature it is recommended for reasons of effectiveness to provide performance feedback to initiate improvement measures immediately after the particular test purchase²³, this was omitted because the student SPs would probably not be accepted by pharmacy staff as briefing partners¹⁴.

The restrictions on time and resources and the very high number of pharmacies visited mean that it was also not possible to provide the pharmacies with individual written performance feedback after the test purchases.

Conclusions

In terms of achieving the appropriate outcome, an enormous potential for improvement was identified for community pharmacies in the German state of Mecklenburg-Vorpommern. Furthermore, more questioning and involvement by non-pharmacists was identified as relevant factors influencing the appropriate outcome. There is a further need for research to identify why the advice provided is so often poor and particularly why the quality of advice provided by pharmacists is so inadequate. The results should make both the Mecklenburg-Vorpommern pharmacy association and legislators aware of the need to significantly escalate their quality management efforts. In this context appropriate mandatory continuing education courses as well as regular independent reviews with an adequate sanction mechanism could provide a stimulus to sustainably improve the quality of advice^{73,74}.

Data availability

Underlying data

Harvard Dataverse: Replication Data for: Do north-eastern German pharmacies recommend a necessary medical consultation for acute diarrhoea? Magnitude and determinants using a simulated patient approach, <https://doi.org/10.7910/DVN/5KVLW4>⁷⁵

Data are available under the terms of the [Creative Commons Zero "No rights reserved" data waiver](#) (CC0 1.0 Public domain dedication).

Acknowledgements

The authors thank the four master students for acting as simulated patients.

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Version 1

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Subish Palaian

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I enjoyed reading the manuscript. It is a well conducted study with robust methodology and focusing on 'community pharmacist referral' which is an important aspect of community pharmacy practice. I thank the F1000Research for providing me the opportunity in reviewing this manuscript. The 'simulated client method' used in this research is suitable in evaluating the real-life practice happening at the community pharmacies.

I have few concerns associated with the manuscript and are as below:

Abstract:

- The result section of the abstract mentions about 'non-pharmacist'. It would be nice to elaborate more on those non-pharmacists somewhere in the Introduction section. Though it is mentioned in the Results, para 2, one would like to know whether non-pharmacists are allowed to dispense medications. This may be useful for international readers. Similarly, in the result part the statement 'two or more questions as opposed to no questions were significantly associated with a referral to a doctor' doesn't appear to be novel. It is understood that someone who had not asked any question will be unable to refer. Authors might consider other observations to be mentioned at this section of the abstract.

Introduction:

- The paragraph 6, authors need to clearly mention which 'baseline' and 'follow-up' study are they mentioning. What is the relation between the current study and those previous studies. Are they the same sample?
- I also found some similarity with few of the previous publications by the author using the same 'acute diarrhea' scenario. Authors need to verify the contents and avoid any

similarities.

- May be the Introduction section should elaborate more on the justification of this research. Why did all these studies used only 'acute diarrhea' as the scenario? This needs further elaboration.

Methodology

- Under scenario and assessment, it is not clear how authors categorized 'Diarrhoea being present for five days as well as a high fever (40°C) are both considered to exceed the limits of self-medication'. I suppose even if there is presence of mucus and/or blood in the stool may be considered referral. I suggest more explanation on development of the scenario and content validation and why 'Dysentery' was excluded from the scenario.

Results:

- In this research, 45.2% of the dispensers were 'non-pharmacists'. If that is the case then how can we correlate the research findings to evaluate the Community Pharmacy practice? The term 'non-pharmacist' needs more elaboration. Probably in the Introduction section, as I mentioned elsewhere.
- Table 4, response 8. Dispensing of a medication 175 (87.9%). What were these medications. Were there any antibiotics? What happened to the rest 22.1%? Why they did not dispense medications? These are some missing information and needs to be incorporated in the Results section.

Discussion:

- The discussion can focus on reason for non-referral by the pharmacists. Are there skills related issues? Do the pharmacists possess adequate skills in assessing patients with diarrhea? These aspects may further enrich the discussion.

Limitations:

- Authors could explore any seasonal impact on the finding.

Is the work clearly and accurately presented and does it cite the current literature?

Yes

Is the study design appropriate and is the work technically sound?

Yes

Are sufficient details of methods and analysis provided to allow replication by others?

Yes

If applicable, is the statistical analysis and its interpretation appropriate?

I cannot comment. A qualified statistician is required.

Are all the source data underlying the results available to ensure full reproducibility?

Yes

Are the conclusions drawn adequately supported by the results?

Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Pharmacy Practice, Pharmacovigilance, Pharmacoepidemiology

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 24 Apr 2020

Bernhard Langer, University of Applied Sciences Neubrandenburg, Neubrandenburg, Germany

We would like to thank the reviewer for taking the time to review our manuscript and also for the very helpful and detailed comments, recommendations and questions. See our point-by-point response to the reviewer's comments below.

I enjoyed reading the manuscript. It is a well conducted study with robust methodology and focusing on 'community pharmacist referral' which is an important aspect of community pharmacy practice. I thank the F1000Research for providing me the opportunity in reviewing this manuscript. The 'simulated client method' used in this research is suitable in evaluating the real-life practice happening at the community pharmacies.

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Abstract:

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Thank you for this comment. The following sentence has been added to the background section of the abstract: 'In Germany, non-pharmacists (pharmacy technicians and pharmaceutical technical assistants) are permitted to advise on and sell medications in addition to pharmacists.'

- Similarly, in the result part the statement 'two or more questions as opposed to no questions were significantly associated with a referral to a doctor' doesn't appear to be novel. It is understood that someone who had not asked any question will be unable to refer. Authors might consider other observations to be mentioned at this section of the abstract.

Thank you for this comment. We replaced the statement 'two or more questions as opposed to no questions were significantly associated with a referral to a doctor' with other observations.

Introduction:

- The paragraph 6, authors need to clearly mention which 'baseline' and 'follow-up' study are they mentioning. What is the relation between the current study and those previous studies. Are they the same sample?

Thank you for this comment. We expressed ourselves misleadingly. To clarify, the sentence has been restructured as follows: 'Despite the two studies from 2014 and 2017 mentioned above, there remains a lack of information about the quality of advice for the indication acute diarrhoea in Germany. The reason is that the four scenarios investigated in these two studies were designed as 'moderate', in that referral to a medical consultation by the pharmacy staff was not mandatory in any of the scenarios.' Also to clarify, the word 'current' has been added to this sentence: 'The aim of this current study was, therefore, to determine on the basis of a considerably larger number of pharmacies whether the pharmacy staff referred patients to a medical consultation for a scenario in which consulting a doctor was mandatory ('appropriate outcome') and what the quality of questioning and – if a medication was dispensed – the quality of information provided were in this context.' The following sentence was also added to the design subsection in the methods section: 'It must once more be explicitly emphasized that this study shares no similarities with the previous studies conducted in 2014 and 2017 apart from the indication investigated (acute diarrhoea).'

- I also found some similarity with few of the previous publications by the author using the same 'acute diarrhea' scenario. Authors need to verify the contents and avoid any similarities.

Thank you for this comment. This study and the previous studies investigate the same indication (acute diarrhoea) but do not use the same scenario. As described in the introduction section, the scenarios used in previous studies from 2014 and 2017 were designed as 'moderate' in that in none of the scenarios was a referral for medical consultation by the pharmacy staff mandatory. In contrast, this study determines whether the pharmacy staff referred patients to a medical consultation in a scenario in which consulting a doctor was mandatory. Therefore, it is simulated – unlike the studies from 2014 and 2017 – that the grandmother has had diarrhoea for five days and fever (40°C) (see Table 1). To clarify, the following sentence has been added to the design subsection in the methods section: 'It must once more be explicitly emphasized that this study shares no similarities with the previous studies conducted in 2014 and 2017 apart from the indication investigated (acute diarrhoea).'

- May be the Introduction section should elaborate more on the justification of this research. Why did all these studies used only 'acute diarrhea' as the scenario? This needs further elaboration.

Thank you for this comment. As mentioned in the introduction section, there are studies available from Germany regarding the quality of advice provided in pharmacies but none for this indication. To better clarify why three research studies for acute diarrhoea are necessary, the sentences have been restructured as follows: 'Because of this lack of studies for acute diarrhoea, the quality of advice provided for acute diarrhoea in adults was analysed for Germany for the first time in 2014 and also identified clear deficiencies. Despite performance feedback used in the process to improve the quality of advice, a follow-up study in 2017 identical to that conducted in 2014 again showed poor quality of advice.' And furthermore: 'Despite the two studies from 2014 and 2017 mentioned above, there remains a lack of information about the quality of advice for the indication acute diarrhoea in Germany. The reason is that the four scenarios investigated in these two studies were designed as "moderate", in that referral to a medical consultation by the pharmacy staff was not mandatory in any of the scenarios.'

Methodology

- Under scenario and assessment, it is not clear how authors categorized 'Diarrhoea being present for five days as well as a high fever (40°C) are both considered to exceed the limits of self-medication'. I suppose even if there is presence of mucus and/or blood in the stool may be considered referral. I suggest more explanation on development of the scenario and content validation and why 'Dysentery' was excluded from the scenario.

Thank you for this comment. More explanation on development of the scenario and content validation has been given. Additionally, it has been explained why 'Dysentery' was excluded from the scenario. Therefore, the relevant sentences have been restructured as follows: 'The tool provided by the Federal Chamber of Pharmacies indicates 10 possible reasons (such as diarrhoea present > two to three days; fever > 39°C; blood or mucus in the stool; change from diarrhoea to constipation) each of which, if present, are considered to exceed the limits for self-medication and should result in the recommendation to consult a doctor. For this reason, a scenario was designed in which the grandmother's diarrhoea had already been present for five days and she also had a fever of 40°C. Blood or mucus in the stool as another possible indication that the limits of self-medication had been exceeded was not considered in the scenario because it did not appear realistic for a grandmother to share this intimate information with her grandchildren. Therefore, if the pharmacy staff asked the SPs about the presence of blood in the grandmother's stool, the SPs stated that it was not known whether there was blood in the stool.'

Results:

- In this research, 45.2% of the dispensers were 'non-pharmacists'. If that is the case then how can we correlate the research findings to evaluate the Community Pharmacy practice? The term 'non-pharmacist' needs more elaboration. Probably in the Introduction section, as I mentioned elsewhere.

Thank you for this comment. The following sentence has been added to the introduction section to better explain the term 'non-pharmacist': "In Germany, non-pharmacists (pharmacy technicians and pharmaceutical technical assistants) are permitted to advise on and sell medications in addition to pharmacists."

- Table 4, response 8. Dispensing of a medication 175 (87.9%). What were these medications. Were there any antibiotics? What happened to the rest 22.1%? Why they did not dispense medications? These are some missing information and needs to be incorporated in the Results section.

Thank you for this comment. The relevant sentences have been restructured as follows: 'In 87.9% (n=175) of all visits a medication was dispensed, whereas in 22.1% (n=24) of all visits no medication was dispensed. Regarding the visits in which a medication was dispensed, in 77.2% (n=135) of visits loperamide was dispensed and in 11.4% (n=20) probiotics were dispensed, whereas, for example, antibiotics that require a prescription in Germany were not dispensed at all.' As described previously in the methods section, the guidelines expect that for such a condition that pharmacists are free to determine whether they also dispense a medication in addition to a mandatory referral to a doctor. It is therefore no wonder that a medication was not dispensed in all test purchases.

Discussion:

- The discussion can focus on reason for non-referral by the pharmacists. Are there skills related issues? Do the pharmacists possess adequate skills in assessing patients with diarrhea? These aspects may further enrich the discussion.

Thank you for this comment. To further enrich the discussion, the following sentence and an additional reference has been added: 'In regards to a lack of knowledge, pharmacists should receive greater training during their studies in patient consultations using examples ⁴⁴, especially as to date the teaching of such 'soft skills' in German universities has been below average compared to other European countries ⁵⁵.'

Limitations:

- Authors could explore any seasonal impact on the finding.

Thanks a lot for this comment. The following sentence and an additional reference to the limitations have been added: 'Carrying out the visits in winter only may have had a seasonal impact on the findings because the pharmacy staff may possibly have been more aware of this indication due to the increased occurrence of acute diarrhoea in the winter months and therefore the results of our study may have been better than at other times of the year ⁷⁴.'

Competing Interests: No competing interests were disclosed.

Reviewer Report 10 February 2020

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Suleiman I. Sharif

Department of Pharmacy Practice and Pharmacotherapeutics, College of Pharmacy, University of Sharjah, Sharjah, United Arab Emirates

I thank you for trusting me with the review of this article which presents a well-designed and executed study. I do approve of indexing the article after some answers and minor corrections to be provided by the authors.

1. Ethical approval: I appreciate that in this study obtaining a written consent from the staff of the pharmacies would have greatly and negatively impacted the results and any "appropriate outcome" obtained would have been a biased one.
2. Pre-piloting the scenario with other than the researchers may have improved the approach.
3. The SPs made their request to the pharmacy staff who first approached them. Were the SPs certain whether "the pharmacy staff who first approached them" a pharmacist or pharmacy technician? In table 3, about 72% were not pharmacist and not able to determine. Moreover, the authors stated in the results that "In most of the test purchases, the advising pharmacy staff were females, between 30 and 49 years of age and did not have a pharmacy degree (non-pharmacist)". Since those they should practice under the supervision of a pharmacist, the authors need to elaborate on this in relation to their discussion where they state "Non-pharmacists (pharmaceutical technical assistants and pharmacy technicians) have a significantly higher likelihood of achieving the appropriate outcome than pharmacists".
4. Point 2 must be also discussed in relation to their conclusion where they state "Furthermore, more questioning and involvement by non-pharmacists was identified as relevant factors influencing the appropriate outcome. There is a further need for research to identify why the advice provided is so often poor and particularly why the quality of advice provided by pharmacists is so inadequate".
5. In table 5, under Queue and Number of questions asked the percentages do not total to 100%. Therefore, the authors need to check their original data, or declare "Missing data" in the table to total the percentage to 100%.

Is the work clearly and accurately presented and does it cite the current literature?

Yes

Is the study design appropriate and is the work technically sound?

Yes

Are sufficient details of methods and analysis provided to allow replication by others?

Yes

If applicable, is the statistical analysis and its interpretation appropriate?

Yes

Are all the source data underlying the results available to ensure full reproducibility?

No source data required

Are the conclusions drawn adequately supported by the results?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Drug Utilization Studies, Pharmacy education, Pharmacy Practice ,
Neuropharmacology

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Author Response 24 Apr 2020

Bernhard Langer, University of Applied Sciences Neubrandenburg, Neubrandenburg, Germany

We would like to thank the reviewer for taking the time to review our manuscript and also for the very helpful and detailed comments, recommendations and questions. See our point-by-point response to the reviewer's comments below.

I thank you for trusting me with the review of this article which presents a well-designed and executed study. I do approve of indexing the article after some answers and minor corrections to be provided by the authors.

- Ethical approval: I appreciate that in this study obtaining a written consent from the staff of the pharmacies would have greatly and negatively impacted the results and any "appropriate outcome" obtained would have been a biased one.

Thank you for this comment. Yes, that is why we did not ask for consent to participate in advance. To clarify, the relevant sentence has been restructured as follows: 'CPs were not asked for consent to participate prior to the study being conducted because obtaining written consent would have significantly and negatively impacted the results.' Additionally, the following sentence was added: 'To resolve the issue of informed consent, the authors contacted the CPs by mail and email after the study informing them that an SP study had been conducted with the corresponding background information ^{48, 49}.'

- Pre-piloting the scenario with other than the researchers may have improved the approach.

Thank you for this comment. Therefore, the following sentences and an additional reference have been added to the limitations: ‘Conducting the pilot study with persons other than the researchers may have improved the approach’⁷³, because the perspective of persons not involved in developing the study design would have been considered. On the other hand, carrying out the pilot study also aimed to train the SPs in the use of the methodology, which again would no longer have been possible.’

- The SPs made their request to the pharmacy staff who first approached them. Were the SPs certain whether “the pharmacy staff who first approached them” a pharmacist or pharmacy technician?

Thank you for this comment. This information was given in Table 2: ‘Exact measurement based on the name tag, the receipt and, if necessary, using a telephone query by the SP after completing the test purchase.’ Despite these efforts, the professional group of the pharmacy staff could not be determined in 55 of 199 test purchases.

- In table 3, about 72% were not pharmacist and not able to determine. Moreover, the authors stated in the results that “In most of the test purchases, the advising pharmacy staff were females, between 30 and 49 years of age and did not have a pharmacy degree (non-pharmacist)”. Since those they should practice under the supervision of a pharmacist, the authors need to elaborate on this in relation to their discussion where they state ‘Non-pharmacists (pharmaceutical technical assistants and pharmacy technicians) have a significantly higher likelihood of achieving the appropriate outcome than pharmacists.’

Thank you for this comment. We have expressed ourselves misleadingly. Therefore, we have deleted ‘but only under the supervision of pharmacists’ in the introduction. To better explain the word ‘non-pharmacist’, we have additionally restructured the sentence as follows: ‘In Germany, non-pharmacists (pharmacy technicians and pharmaceutical technical assistants) are permitted to advise on and sell medications in addition to pharmacists.’ Therefore, we believe that the sentence ‘Non-pharmacists (pharmaceutical technical assistants and pharmacy technicians) have a significantly higher likelihood of achieving the appropriate outcome than pharmacists.’ in the discussion section is now clearer.

- Point 2 must be also discussed in relation to their conclusion where they state “Furthermore, more questioning and involvement by non-pharmacists was identified as relevant factors influencing the appropriate outcome. There is a further need for research to identify why the advice provided is so often poor and particularly why the quality of advice provided by pharmacists is so inadequate”.

Thank you for this comment. Please see our remarks to your point 3. We have deleted

'but only under the supervision of pharmacists' and have restructured the relevant sentence in the introduction section as follows: 'In Germany, non-pharmacists (pharmacy technicians and pharmaceutical technical assistants) are permitted to advise on and sell medications in addition to pharmacists.' Therefore, we believe that the sentences 'Moreover, two or more questions and, surprisingly, the involvement of non-pharmacists were identified as relevant factors influencing the appropriate outcome.' in the conclusions and 'The findings of this study recommend further research to identify why the advice provided is so often poor and particularly why the quality of advice provided by pharmacists is so inadequate.' in the study recommendations is easier to understand.

- In table 5, under Queue and Number of questions asked the percentages do not total to 100%. Therefore, the authors need to check their original data, or declare "Missing data" in the table to total the percentage to 100%.

Thank you for this comment. We have checked all percentages reported in tables and made corrections if necessary.

Competing Interests: No competing interests were disclosed.

Reviewer Report 15 November 2019

<https://doi.org/10.5256/f1000research.23162.r56075>

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Mohamed Izham Mohamed Ibrahim

Department of Clinical Pharmacy and Practice, College of Pharmacy, Qatar University, Doha, Qatar

Thank you for allowing me to review this article. It is an interesting study using an interesting approach i.e. SP. I have a few comments:

1. The conclusion in the abstract section must be consistent with the objective of the study and main findings.
2. Percentages reported in tables must equal to 100% - kindly check all figures.
3. Tables cited in the main text should in proper order.
4. Even though due to the nature of the study, subjects selected were not asked for consent, did the authors contact them after the study informing that a study was conducted with reasons? This is one way that the researchers could resolve the issue of informed consent prior to the study.

5. Create a paragraph on Study recommendations at the end of the Discussion section. Consider to move some parts of the conclusion. Rewrite the conclusion section.

Is the work clearly and accurately presented and does it cite the current literature?

Yes

Is the study design appropriate and is the work technically sound?

Yes

Are sufficient details of methods and analysis provided to allow replication by others?

Yes

If applicable, is the statistical analysis and its interpretation appropriate?

Yes

Are all the source data underlying the results available to ensure full reproducibility?

Yes

Are the conclusions drawn adequately supported by the results?

No

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Social-behavioral and Administrative aspects of health and pharmacy

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 24 Apr 2020

Bernhard Langer, University of Applied Sciences Neubrandenburg, Neubrandenburg, Germany

We would like to thank the reviewer for taking the time to review our manuscript and also for the very helpful and detailed comments, recommendations and questions. See our point-by-point response to the reviewer's comments below.

Thank you for allowing me to review this article. It is an interesting study using an interesting approach i.e. SP. I have a few comments:

- The conclusion in the abstract section must be consistent with the objective of the study and main findings.

Thank you for this comment. The conclusion has been restructured to be consistent with the objectives of the study and main findings.

- Percentages reported in tables must equal to 100% - kindly check all figures.

Thank you for this comment. We have checked all percentages reported in tables and made corrections if necessary.

- Tables cited in the main text should in proper order.

Thank you for this comment. We have ensured that the tables are cited in the correct order.

- Even though due to the nature of the study, subjects selected were not asked for consent, did the authors contact them after the study informing that a study was conducted with reasons? This is one way that the researchers could resolve the issue of informed consent prior to the study.

Thank you for this comment. Yes, we contacted the subjects after the study informing them that an SP study was conducted with reasons. Therefore, the following sentence and two additional references have been added: 'To resolve the issue of informed consent, the authors contacted the pharmacies by mail and email after the study informing them that an SP study had been conducted with the corresponding background information ^{48, 49}.'

- Create a paragraph on Study recommendations at the end of the Discussion section. Consider to move some parts of the conclusion. Rewrite the conclusion section.

Thank you for this comment. We have created a new paragraph on study recommendations at the end of the discussion section and have moved some parts of the conclusion to this new paragraph. Additionally, the conclusions section has been rewritten.

Competing Interests: No competing interests were disclosed.

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