Dietary advice for acute diarrhoea in general practice: a pilot study

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SUMMARY

Background. *Although there is no evidence that diet shortens acute diarrhoea, doctors tend to give dietary advice.*

Aim. *To test the effects of eating and drinking normally on the duration of acute diarrhoea and on the feeling of well-being.*

Method. *Randomized single-blinded, controlled trial in urban and semi-urbanized areas. Patients aged 3–70 years suffering with diarrhoea at least three times on the preceding day, lasting no more than five days, were eligible. Two regimes were randomly allocated to practices. In the intervention group, the advice was to eat everything one liked and to drink more. The control group was advised to follow a strict regime of fasting for 24 hours and was subsequently given specified limitations.*

Results. *No significant differences between the 44 patients in the intervention group and the 27 in the control group were found for the duration of watery diarrhoea (median 14 versus 13 hours), or the total number of evacuations (2 versus 2.5). Among the items concerning well-being, only nausea (51% versus 23%) showed a significant difference.*

Conclusion. *In this pilot study, the null hypothesis that both treatments will show equal results cannot be confirmed or rejected because of the small number of participants. Despite our efforts, we included fewer patients than expected. This might be due to the data-forms, which were rather complicated and voluminous for both, including doctors and participants.*

Keywords: diet; diarrhoea; general practice.

Introduction

IN developing countries, well-hydrated children suffering from acute diarrhoea tolerate breastfeeding well,[1] and also undiluted cow-milk formula[2-4] or rapid refeeding;[5-9] however, doctors appear to continue to give traditional advice.[10-12] In a postal inquiry, 70% of Dutch general practitioners (GPs) reported advising their patients to stop taking solid foods for a considerable period of time.[13] A minority of GPs advised 'not to continue breast-feeding' and the majority gave varied advice, either discouraging or recommending specific food and drink. Only 20% of the GPs reported a policy that was in accordance with recent guidelines produced by the Dutch College of General Practitioners.[14]

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In developing countries, limited calorie intake during recurrent periods of diarrhoea leads to malnutrition; this itself is a risk for diarrhoea. In well-fed western children, this is not likely to occur, but starvation and diluting drinks might make a child feel less well.[8]

We are unaware of a controlled clinical trial that compares normal feeding with starvation and feeding limitations in a developed country. In a pilot study in general practice, we intended to test the effects of eating and drinking normally, both on the duration of acute diarrhoea and on patients' feelings of well-being.

Subjects and Methods

Design

The study was single-blinded and controlled. Participants were advised to adhere to one of two dietary regimes.

Doctors were recruited among trainees of the vocational training department of the Vrije Universiteit and acquaintances. All received personal instructions on informing participants. For the recruiting doctors, giving completely different advice was undesirable; therefore, each practice was randomly assigned one treatment regime. This nested method is both reliable and accepted in complex intervention studies.[15,16] Owing to the incidence of acute diarrhoea having been recorded for between three and nine patients per 1000,[17,18] we expected each doctor to include one patient a month, bringing in a total of 240 participants. The Committee on Ethics of the Vrije Universiteit in Amsterdam approved the study.

Subjects

Patients were recruited in general practices in urban and semi-urbanized areas in the Netherlands. Patients had to be aged over three years but not older than 70 years. Diarrhoea had to be watery or unformed at least three times in the preceding 24 hours and in no more than 120 hours. Patients or their parents needed a working knowledge of Dutch.

Criteria for exclusion were suspected dehydration, another member of the family also participating, formed faeces, other known causes of diarrhoea, treatment with radiotherapy, cytostatics, or prednison.

Intervention

Information about causes, course, seriousness, measures to be taken for abdominal cramps or vomiting, and when to consult a physician, was intended to be identical in both intervention and control groups. In the intervention group, the dietary advice was to eat everything they liked and to drink more than usual. The control group was subjected to a strict regime that included fasting for 24 hours (Box 1). Controls were encouraged to drink more than usual as well.

Measurements

Baseline characteristics. Biographical data comprised sex, age, and education. Knowledge about diarrhoea was tested by 16 propositions. On principal component analysis, these propositions yielded two factors, explaining 35% of variance: one cluster representing 'traditional knowledge', the other one 'trick

BREAD, etc
white bread, crackers, biscuits, rice pudding, grated apple, banana, thin spreads

SNACKS
crackers, biscuits, breadsticks, grated apple, banana, thin spreads

MAIN MEALS
clear broth, bread sticks, rice, cooked carrots, cooked cauliflower, rice pudding, grated apple, banana

DRINKS (at all times)
water, apple juice, tea with no milk or sugar, rice-water, rose-hip syrup

Box 1. Diet for control group.

questions'.

Sickness in the past five days was determined by the number of watery stools and vomiting, feelings of fever, abdominal pain, or headache. Use of medication — prescribed, as well as self-administered — and prior dietary measures — like not eating and/or drinking — were recorded. Stools were examined for *Salmonella/Shigella* spp, *C. jejuni*, and *Yersinia enterocolitica*, following standardized procedures. Four cell cultures and latex agglutination tests detected the presence of adenovirus and rotavirus. Evidence of protozoa was microscopically tested in sodium acetate acetic acid formalin (SAF) -fixated smears,[19] and *Giardia lamblia* by ELISA-test.[20]

Independent variable. Consumption was to be marked on a daily list that offered pre-printed suggestions. Fasting was defined as consuming no nutrients during the first day. Compliance with the dietary regime was expressed as a ratio: the number of permitted items over the total number consumed. Three measures of compliance were established: the number of participants fasting the first day, and, for every participant, the ratios of permitted items of food and drink. Compliance in the intervention group cannot be measured since the advice was without specifications. Practically, however, it can be detected from the opposite direction: observing restrictions amounts to non-compliance.

Outcome variables. The main outcome variable was the duration of watery and non-watery diarrhoea. During treatment, participants were asked to indicate each occurrence of diarrhoea and vomiting by putting a mark on a list that was divided into 24-hour compartments. Duration was expressed in hours, and intensity was expressed in occurrences per day. Secondary outcome variables were vomiting and well-being. At the end of every day, participants had to record whether they had been able to carry out their regular activities and hobbies. They had to report (yes/no) feelings of weakness, hunger, fever, abdominal pain, nausea or headache, resting or sleeping, taking medication, and contacting their GP.

Patients with unformed stools for more than seven days (168 hours) after inclusion, and hospitalized patients, were considered treatment failures.

Intervening variables. These variables were age, sex, taking medicine prior to inclusion, temporarily not drinking and/or eating, taking loperamide, and presence of pathogenic micro-organisms.

Analysis

All statistical analyses were carried out in SPSS 6.0 for Windows, the participants being the units of analysis. Duration of watery diarrhoea was analysed by Kaplan-Meyer survival analysis and log rank tests.[21] Both the control and intervention groups were compared on baseline characteristics through bivariate contingency tables. Intermediating factors were also analysed using bivariate contingency tables.

Results

Recruitment and randomization

During a period of one year, 84 trainees and 43 GPs recruited 71 participants: 44 in the intervention group and 27 controls. Four participants in the intervention group submitted data unfit for analysis. Three treatment failures occurred: two in the intervention group, and one in the control group. Thus, 38 cases in the intervention group and 26 in the control group could be analysed. One intervention patient supplied limited data and was analysed only on the duration of diarrhoea (Table 3).

Baseline characteristics

The distribution of baseline characteristics (Table 1) showed no significant differences between the two groups. Although not significant, the control group had a slightly higher education level.

Outcome variables

The main outcome, duration of watery diarrhoea, was similar in both groups. Non-watery diarrhoea lasted longer (not significant) in the control group (Table 2). The frequencies of watery and non-watery diarrhoea were approximately equal in both groups. Omitting five participants whose diarrhoea stopped within 24 hours did not change the results.

The intervention group complained significantly more about nausea (51% versus 23%). There were no significant differences in the other secondary outcome variables (i.e. feelings of hunger, fever, weakness, abdominal complaints, headache, sleeping, resting, capability of work and hobbies, and consulting the GP) (Table 3).

Compliance

For controls, compliance meant fasting and adhering to the limited list of permitted items. Ten participants (37%) in the control group refrained completely from consuming food on the first day (Table 5). Compliance for food had a median of 66.7% (interquartile range [iqr] = 44.5–87.5); compliance for drinks amounted to a median of 54.4% (iqr = 35.1–71.0). Compliance for drinks was seen to diminish gradually with time.

In the intervention group, non-compliance was defined as observing restrictions. Thus, non-compliance was found in four (10%) participants when fasting, in eight (15.4%) participants for whom 75% or more of their foodstuffs eaten could be found on the list of restrictions for controls, and in nine (20.5%) who consumed 75% or more of drinks appearing on that list.

After the intention-to-treat analysis, we also tested efficacy of dietary advice by comparing all participants who had observed restrictions for 75% of consumption or more with those who had done so for less than 25% of the time, regardless of the group they belonged to. In this secondary analysis, the duration of watery diarrhoea was 12.5 hours for fasting (95% CI = 0–38.5) versus 11.5 hours (0–27) for non-fasting. Compliance for food for 75% showed 1.0 hour of duration (0–15.5) versus 3.0 hours (0–11.5) for 25% compliance. Participants with 75% compliance for drinks had 12.5 hours (4.3–23.5) of watery diarrhoea versus 4.0 hours (0–25) for 25% compliance. Thus, neither fasting nor adhering to the regime of food or drinks made any difference to the duration of the diarrhoea.

Table 1. Baseline characteristics of the intervention and the control group. Values represent number (percentages) of subjects unless stated otherwise.

	Intervention group (n = 40)		Control group (n = 27)	
	n (iqr)	%	n (iqr)	%
Demographic data				
Women	18	45	13	48
Age (median – quartiles)	32.3 (19.1–43.2)		29.3 (23.3–47.2)	
Highest level of education:				
none (yet)	6	15	5	19
primary	8	20	7	26
secondary	20	50	11	41
academic	5	13	4	15
Prior to illness				
Diet	1	3	1	4
Chronic medication	8	20	4	15
Incidental medication	1	3	4	15
Before admission				
Median (iqr) total number of:				
stools	17.0 (9.0–23.0)		13.6 (9.8–21.3)	
vomiting	0.0 (0.0–2.0)		0.0 (0.0–1.0)	
Days with :				
diarrhoea	3.0 (2.0–4.0)		3.0 (2.0–3.0)	
(feeling) feverish	1.0 (0.0–2.0)		1.0 (0.0–2.0)	
headache	1.0 (0.0–2.0)		1.0 (0.0–3.0)	
abdominal pain	2.5 (2.0–3.8)		3.0 (2.0–4.0)	
Fraction of family with diarrhoea	0.0 (0.0–0.3)		0.0 (0.0–0.2)	
Patients reported having seen:				
Blood in stools	–	–	3	11
mucus in stools	13	33	8	30
Self-administration of drugs:	15	38	9	33
loperamide	2	5	–	–
other anti-diarrhoeal drugs	4	10	3	11
pain-killers	7	18	2	7
other	1	3	–	–
two medicaments	4	10	–	–
More than four hours without drinking anything	6	15	–	–
not drinking with intention to recover	3	8	–	–
More than 12 hours without eating anything	13	33	9	33
not eating with intention to recover	4	10	4	15
Knowledge about diarrhoea[4]				
Traditional knowledge	24.0 (20.0–27.30		19.5 (17.0–21.3)	
Trick questions	15.0 (13.0–15.0)		15.0 (14.8–16.0)	
Laboratory results[5]	n = 36		n = 27	
Micro-organisms:				
bacteria	10	28	7	26
virus	1	3	1	4
pathogenic protozoa	7	19	4	15
no micro-organism	10	28	13	48

Additional data

For most patients, the symptoms started on day three or day two before inclusion; the number of stools was highest on the day of inclusion and the previous day. The overall median duration of diarrhoea was three days (iqr = 2–5).

Discussion

In this pilot study, no significant differences between intervention and control groups were found with regard to the duration of watery diarrhoea, or the number of evacuations or vomiting. Among the items concerning well-being, only nausea (occurring twice as often in the intervention group) showed a significant difference. This might be a result of the normal eating and drinking regime.

Despite our efforts, the total number of participants included did not exceed 67. This might be due to the data-forms, which were rather complicated and voluminous for both doctors and participants. Therefore, there is a greater chance of a type 2 error, and conclusions can only be preliminary. Due to the small number of participants, we refrained from a multi-level analysis, required because of the method of randomization.

Physicians in the intervention group included more cases.

Table 2. Diarrhoea after inclusion (median, iqr).

	Intervention (n = 38)	Control (n = 26)	Log rank test
Duration in hours:			
watery diarrhoea	14 (0–43)	13 (1–24)	0.46; P = 0.50
non-watery diarrhoea	18 (0–71)	42 (0–61)	0.15; P = 0.69
vomiting	0	0	–
Total number of occurrences:			
watery diarrhoea	2.0 (0.5–10.0)	2.5 (1.0–7.0)	
non-watery diarrhoea	1.0 (0.0–6.0)	2.0 (0.0–5.3)	
vomiting	0.0 (0.0–0.0)	0.0 (0.0–0.0)	

Table 3. Well-being. Values represent numbers (percentages) of subjects unless stated otherwise.

	Intervention group n = 37		Control group n = 26		Pearson P-value
	n	%	n	%	
Participants reporting 1 day of:					
Hunger	18	49	17	65	0.19
Abdominal pain	35	95	22	85	0.18
Nausea	19	51	6	23	0.02
Headache	16	43	13	50	0.60
Fever	10	27	11	42	0.21
Weakness	30	81	20	77	0.69
Sleeping more than usual	26	70	16	62	0.47
Resting more than usual	32	87	23	89	0.82
Participants 1 day incapable of:					
Work (completely/partially)	32	87	22	85	0.83
Hobbies/voluntary tasks	32	87	23	89	0.82
Participants who consulted:					
General practitioner	3	8	2	8	0.95
Relative(s)	14	38	5	19	0.11

Since the intervention regime was in accordance with recent guidelines,[14] doctors might be inclined to test this regime, or they might find it hard to advise a regime they do not agree with. Though selection bias could have occurred, both groups were similar at the start.

Since so many doctors still believe in diet as an effective method to influence diarrhoea, it is worth the effort to repeat this pilot on a larger scale. A very simple design is of paramount importance in order to get enough participants. GPs and patients should easily understand what to do and the paperwork should be kept simple.

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