**Research Protocol**

**LOW RISK - QUANTITATIVE STUDIES (INCLUDES WAIVER OF CONSENT)**

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| **Study Title:** | The use of a volitional help sheet for reducing interdialytic weight gain in patients with kidney failure undergoing haemodialysis: A cluster randomised controlled trial. |
| **Protocol Number/Version/ Date:** | *2.0*  *08/07/2024* |
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# PROTOCOL VERSION CONTROL

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| **Version** | **Date** | **Amendment (brief description)** | **Amendment date  (as per amendment form)** |
| 1.0 | 25/04/2024 | 4-study aims and objectives  5.1- study design  5.2-settings  5.6- data sources  5.5- data collection  5.6- data handling  6- statistical analysis plan  7.3- data retention and disposal  9- Appendices | 08/07/2024 |
| 2.0 | 08/07/2024 |  |  |
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# BACKGROUND AND RATIONALE

3.1 ABSTRACT / SUMMARY

Poor self-management of fluid intake in patients with kidney failure who are undergoing haemodialysis can result in fluid overload, which contributes to poor health outcomes and increased mortality (1). Health literacy strategies play an important role in promoting positive behavioural changes to better manage fluid intake.

The aim of this study is to determine the efficacy of a volitional help sheet in promoting behavioural changes that lead to a reduction in fluid intake and interdialytic weight gain in patients with kidney failure on haemodialysis.

3.2. BACKGROUND / RATIONALE

Chronic kidney disease (CKD) is a major health concern in Australia, with an estimated 11% (1.7 million) of Australia’s adult population showing biomedical signs of CKD (2). Whilst the prevalence of CKD has remained stable (0.8-1%) over the past 20 years, the prevalence of treated kidney failure has almost doubled, especially among people aged 75 years and over (2, 3). The burden from CKD is disproportionately amongst Aboriginal and Torres Strait Islander peoples, people living in the most socioeconomically deprived areas and those aged 75 years and over(2, 4). CKD contributes to an ongoing inequity as well as health and economic burden for individuals and the Australian healthcare system, with an estimated $1.9 billion (1.2% of total health budget) of the government’s health expenditure (2020-21) being allocated to CKD. (2, 5).

Health literacy (HL) has been shown to play a critical role in the self-management of CKD, with low HL being an important predictor of poor health outcomes, including increased hospitalisation and mortality rates (6, 7, 8). Poor HL has also been linked to health inequalities, especially among people who are from low socioeconomic status (SES), are of older age and from culturally and linguistically diverse (CALD) populations; the same populations who are also disproportionately impacted by CKD (7). This suggests that patients from these population groups may have more difficulty understanding medical information and adhering to plans related to the management of their chronic disease.

Several interventions have been used to support patients with CKD in self-managing their medical condition. These include digital technologies such as eHealth interventions (Telehealth, mobile Apps, text messaging services, webpages)(9, 10, 11), decision aids and decision coaching (11, 12, 13) and a variety of education programs (11, 14), many of which have been targeted at promoting changes in diet and physical activity but have been shown to have limited efficacy in modifying behaviours (14, 15, 16). Additionally, few studies have targeted modifying behaviours related to fluid intake amongst patients with kidney failure on dialysis. For patients undergoing dialysis, amongst other domains that require self-management, limiting fluid intake is important to prevent complications of fluid overload such as oedema, hypertension, congestive heart failure and pulmonary oedema and an increased risk of hospitalisations, all-cause and cardiovascular mortality (17, 18, 19).

A recent review of the literature (20) found 18 randomised intervention trials, nine of which focused solely on fluid management. These trials evaluated adherence to fluid restrictions in dialysis patients using interventions such as education, decision coaching, behavioural therapies, e-health services and incentivisation, the majority of which measured interdialytic weigh gain (IDWG) and/or self-efficacy as outcomes. Whilst improvements in adherence to fluid restrictions was evident over a short period, long term efficacy for adherence to fluid restrictions in dialysis patients is yet to be established (20). Many of these studies addressed patient-related factors that influence non-adherence to fluid restriction, including anxiety and depression, however, there was little to no evidence that any of the interventions addressed poor health literacy as a factor for non-adherence or incorporated health literacy strategies in their design to self-manage fluid intake among patients on dialysis.

Volitional help sheets (VHS) are a form of behavioural change intervention that are designed to promote health related behavioural change. They work by linking critical situations (“if”) with appropriate behavioural responses (“then”)(21). Previous randomised controlled trials (RCTs) have had successful results from the use of VHS in changing behaviours such as in increasing physical activity in people of low SES (22), improving smoking cessation behaviours (23), reducing unhealthy snacking among people with low health literacy (24) and for reducing alcohol consumption among people who smoke (25). Ayre et al (24) adapted a VHS to contain a simple step-by-step guide to reduce unhealthy snacking by prompting participants to link an “if” situation or “snack moment” with a “then” response or “solution” to replace the action of having a snack. This VHS embedded additional evidence-based strategies such as the use of simple language and visual stimuli to reduce the cognitive demand placed on participants and was shown to have positive outcomes for participants with low health literacy (24, 26, 27). However, there has been no evidence in the literature of studies that have tested the efficacy of VHS in managing fluid intake among patients on dialysis to date. The goal of our study is to address this research gap by developing a VHS that will model the health literacy strategies developed by Ayre et al (24) for managing fluid intake to prevent fluid overload in patients on haemodialysis (HD).

# STUDY AIMS AND OBJECTIVES

The primary aim of this study is to determine the efficacy of a volitional help sheet in promoting behavioural changes that lead to a reduction in interdialytic weight gain in patients with kidney failure on haemodialysis.

Further objectives of this study will be to determine the (i) feasibility of the recruitment measures, (ii) feasibility of the randomisation procedures, (iii) the acceptability and suitability of intervention materials and (iv) the efficacy of the volitional help sheet in reducing interdialytic weight gains. This phase of the study (Phase 1-Pilot study) is intended to inform a full-scale cluster randomised controlled trial (Phase 2-definitive study).

# METHODS

* 1. STUDY DESIGN

The study design will take the form of a cluster randomised controlled trial (RCT) to compare the use of a volitional help sheet (VHS) in reducing inter-dialytic weight gains to usual care among patients on HD over a 12-week period.

The intervention consists of a VHS that links “if” and “then” behaviours relating to fluid intake. Participants will choose at least one of five common “if” situations, including “I am often tempted to drink too much fluid” when “I am thirsty”, “I am out with other people” and/or “I have had too much salt in my diet”. Participants will make their plan by linking an “if” behaviour such as “If I'm tempted to drink a lot of fluid because I am thirsty, then I will” to a “then” behaviour such as “only have half a cup of drink” or “suck on a few ice cubes and limit this to one cup per day”.

The intervention will be tested in two phases;

1. Phase 1- Pilot study

An initial pilot study will be used to assess the feasibility of the study procedures (recruitment, randomisation and acceptability of the intervention components) in addition to the main study outcomes, before continuation to a full-scale cluster randomised controlled trial (Phase 2).

1. Phase 2- definitive study to test the efficacy of the VHS in reducing interdialytic weight gain.

The VHS will be presented to consenting participants, in paper format, who have been allocated to the intervention group following recruitment. Researchers will check-in with participants at weeks four and eight to remind them of their if-then plans, and to check on their progress in using the plan. Participants who indicate that their plan is not working effectively, will be given the option to create a new plan. Participants who consent to be contacted by phone, will be sent a reminder text for the check-in. Alternatively, researchers may visit the study sites in person at weeks four and eight to check-in on participant progress. (see Appendix A, Appendix B).

* 1. SETTING

Participants will be recruited from Blue Mountains District ANZAC Hospital (Katoomba Community Dialysis Centre), Nepean Hospital Department of Renal Medicine, Nepean Satellite Dialysis Unit (Penrith Community Dialysis Centre) and Westmead dialysis in-centre and satellite haemodialysis units. Recruitment is intended to take place from August 2024-June 2025. Informed consent and completion of demographic survey will be completed during the recruitment period. Follow up and data collection is intended to take place over a 12-week period following recruitment from September 2024-December 2025.

* 1. METHODOLOGY

Cluster randomisation will be based on the days that participants receive haemodialysis, rather than by individuals. This approach is more practical to implement and has the potential to prevent contamination, where participants in the control could arm could be exposed to the intervention materials. This is because patients receive haemodialysis treatment in open rooms within the hospital setting, for several hours a day, often 3 times a week, either on Monday, Wednesday and Fridays or Tuesday, Thursday and Saturday (28). At each dialysis site, days of the week (Monday, Wednesday and Friday vs Tuesday, Thursday and Saturday) will be randomly allocated to intervention groups, using the simple randomisation function of the Study Randomizer online tool (29). This approach has been adapted from previous RCTs in hospital dialysis settings.

Baseline measurements and participant characteristics will be taken upon recruitment. This will include age, gender, weight, Aboriginal and Torres Strait Islander status, country of birth, ethnicity, highest level of education completed, health literacy, postcode, language spoken other than English and time on dialysis (months). Baseline measurements will be collected at the beginning of the study by the researchers following participant consent. (see Appendix C).

* 1. STUDY POPULATION/PARTICIPANTS

INCLUSION CRITERIA

1. Stage 5 chronic kidney disease.
2. Adults ≥ 18 years.
3. Receive haemodialysis treatment ≥ 3 times/week at participating sites.
4. Have high interdialytic weight gain (>10% dry weight).
5. Basic English skills.
6. Willingness to provide informed consent and participate and comply with the study requirements.

EXCLUSION CRITERIA

1. Lacks capacity to provide informed consent as determined by the treating clinician.
2. Diagnosis of dementia or severe cognitive impairment.
3. Cannot read, write or speak any English as the Volitional Help Sheet, behaviour and confidence surveys are only available in English.

KEY ELEMENTS OF RECRUITMENT

Passive and active recruitment will take place simultaneously over a 12-week period.

Passive recruitment

A4 flyers will be distributed at each dialysis site and will include an invitation to participate, the purpose of the research project, what participation will involve and the eligibility criteria. Interested participants will have the option to scan the QR code on the flyer to access the digital Participant Information Sheet/consent form. Researchers will be on site to address any questions that potential participants may have and will be available to go through the participant information sheet with patients that are interested in taking part in the project. Participants who do not own a smart device will be invited to use tablets provided by the researchers. (see Appendix D, Appendix E, Appendix F).

Active recruitment

Eligible patients at each dialysis site will be identified by the Principal Investigators at each site and will be approached by the researchers during their scheduled dialysis sessions to explain the purpose of the research project, what the participation involves, any risks, their rights to choose to participate and/or withdraw from the study and issues relating to privacy and confidentiality before informed consent can be obtained. Participants who do not own a smart device will be invited to use tablets provided by the researchers for the completion of consent forms. (see Appendix E, Appendix F).

RECRUITMENT AND CONSENT

Written informed consent will be collected from all participants who verbally indicate their interest in being a part of the study during the recruitment process. Participants will be given time to read the participant information sheet and consent form and will have the opportunity to ask researchers any questions regarding the study and the conditions of their consent. Participants will be given the time to consider their options and may choose to fill out the consent form at during the following dialysis session. (see Appendix G).

Participants will be informed of their right to withdraw from the study at any time by filling out a Form for withdrawal of participation. (see Appendix H).

* 1. DATA SOURCES

|  |
| --- |
| Already available, e.g. EMR, clinical notes, other system  Yet to be collected |

5.5. DATA COLLECTION

Quantitative Data

Dialysis nurses will enter routinely collected data on participant pre-dialysis weight and pre-dialysis blood pressure into the Electronic Medical Records (eMR) system, and the Principal Investigators for this study will directly extract this data from eMR at the conclusion of the study (Week 12 post commencement). Researchers will directly enter this data on the University of Sydney’s (USYD) REDCap database.

Researchers will approach participants at baseline and at the conclusion of the study (week 12) for completion of the Health Behaviour and Confidence surveys. Participants who have their own devices will be emailed a link or can scan a QR code to access the Health Behaviour and Confidence surveys whilst the researchers are on site. Participants who do not have access to a smart device, will be invited to use a tablet provided by the researchers. All participants will also be given the option for the researcher to enter their responses directly into REDCap.

Baseline measurements and participant characteristics will be taken upon recruitment, after the participant has read the information statement and signed the consent form. This will include age, gender, weight, Aboriginal and Torres Strait Islander status, country of birth, ethnicity, highest level of education completed, health literacy, postcode, language spoken other than English and time on dialysis (months). Refer to ‘Patient Registration’ Version 1.0. (see appendix C)

Participant pre- and post-dialysis weight will be measured by a nurse (centre/satellite units) during each dialysis sessions, for a total of twelve weeks. Pre- and post-dialysis weight is routinely collected for all patients who undergo haemodialysis treatment for kidney failure. Dialysis nurses or Principal Investigators for this study will directly extract this data from eMR at 4-week intervals, and the researchers will directly enter this data to the participant weight log in the USYD REDCap database, from which the interdialytic weight gains (IDWG) and average IDWGs will be calculated. Researchers will not have direct access to patient records at any time. (see Appendix J).

Pre-dialysis blood pressure (BP): Pre-dialysis BP, a surrogate marker for fluid overload (30), will be measured by a nurse (in-centre/satellite units) before each dialysis sessions for a total of twelve weeks. Pre-dialysis systolic blood pressure is routinely collected for all patients who undergo haemodialysis treatment for kidney failure. Dialysis nurses will enter participant pre-dialysis BP into eMR. Dialysis nurses or Principal Investigators for this study will directly extract this data from eMR at 4-week intervals and the researchers will enter this data to the participant blood pressure log in the USYD REDCap database. Average pre-dialysis systolic blood pressure will be calculated from this data. Researchers will not have direct access to patient records at any time. (See Appendix K).

Health Behaviour: A theory informed 8-item pre- and post-behaviour questionnaire, adapted from previous literature (31), will be used to determine behaviours that patients have adopted from the VHS. The survey will include, for example, “Over the past four weeks I have kept track of the amount of fluid I had each day”. Items will be rated on a 5-point ordinal scale ranging from 1(“strongly disagree”) to 5 (“strongly agree”). Researchers will approach participants at the conclusion of the study (week 12) to collect data from the (see Appendix L).

Confidence: An 8-item pre- and post-confidence questionnaire adapted from the Self-Management Resource Centre (32) will be used to measure patient confidence related to the health behaviour survey. The survey will include questions such as “How confident do you feel that you can meet your daily fluid target?”. Items will be rated on a 5- point ordinal scale ranging from 1 (“not at all confident”) to 5 (“extremely confident”). Researchers will approach participants at baseline and at the conclusion of the study (week 12) to collect data for the Health Behaviour survey. (see Appendix M).

Additional Qualitative data- Pilot study

Semi-structured interviews will be conducted by researchers to collect qualitative data at the conclusion of the study (week 12 post commencement). The questionnaire, adapted from Sekhon’s Theoretical Framework of Acceptability(33) will be used to assess acceptability of the volitional help sheet. (see Appendix N). The interview questions will address affective attitude, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness and self-efficacy related to the use of the volitional help sheet VHS (33).

Semi-structured interviews with control group participants will be conducted by researchers to collect qualitative data at the conclusion of the study (week 12 post commencement). The questionnaire will be used to assess feasibility of randomization, specifically to assess whether contamination of the intervention materials has occurred. (see Appendix O).

**Table 1.0: Timeline for collection of participant data**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Week | | | | |  |  |  |  |  |  |  |  |
| Baseline (0) | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| Informed consent | X |  |  |  |  |  |  |  |  |  |  |  |  |
| Demographic survey | X |  |  |  |  |  |  |  |  |  |  |  |  |
| Pre-intervention behaviour survey | X |  |  |  |  |  |  |  |  |  |  |  |  |
| Pre-intervention confidence survey | X |  |  |  |  |  |  |  |  |  |  |  |  |
| Pre- and post-dialysis weight |  | X | X | X | X | X | X | X | X | X | X | X | X |
| Average interdialytic weight gain |  |  |  |  | X |  |  |  | X |  |  |  | X |
| Behaviour survey | X |  |  |  |  |  |  |  |  |  |  |  | X |
| Confidence survey | X |  |  |  |  |  |  |  |  |  |  |  | X |
| Pre-dialysis BP |  | X | X | X | X | X | X | X | X | X | X | X | X |
| Average Pre-dialysis BP |  |  |  |  | X |  |  |  | X |  |  |  | X |
| Additional qualitative data (pilot study-phase 1) | | | | | | | | | | | | | |
| Acceptability questionnaire |  |  |  |  |  |  |  |  |  |  |  |  | X |
| Feasibility of randomisation questionnaire |  |  |  |  |  |  |  |  |  |  |  |  | X |

5.6. DATA HANDLING

All surveys will be set up in the University of Sydney’s REDCap database. Participants will access and complete the surveys using their own smart device. Participants who do not own a smart device will be invited to use tablets provided by the researchers for access and completion of the surveys. The data will be verified for accuracy and completeness, ensuring missing values or errors are corrected. Participant records that contain incomplete data will be removed from the final data collection and will be excluded from the analysis. Final data collection will be coded for analysis.

*Main outcome variable(s)*

|  |  |  |
| --- | --- | --- |
| ***Main outcome variable*** | ***Source of data*** | ***Measure*** |
| *Interdialytic weight gain* | Participant pre-and post-dialysis weight to be collected and entered into eMR by dialysis nurses. Reported to researchers by PI at week 12 (post commencement) | Body weight (kg) |
| ***Secondary outcome variable*** | ***Source of data*** | ***Measure*** |
| *Pre- and post-Behaviour survey* | Pre- and post-participant questionnaire at baseline and conclusion of study | Theory informed 8-item behaviour questionnaire, adapted from previous literature (31). |
| *Pre- and post-Confidence survey* | Pre- and post-participant questionnaire at baseline and conclusion of study | 8-item confidence questionnaire adapted from the Self-Management Resource Centre (32). |
| *Pre-dialysis systolic BP* | Collected by dialysis nurses and reported to researchers by PI at week 12 (post commencement) | Blood pressure (mm/Hg) |
| ***Main outcome variables*** | ***Source of data*** | ***Measure*** |
| Feasibility of the recruitment measures | REDCap tracking database | Percentage of potential participants that meet the inclusion criteria and consent to participation and randomisation (34).  Participant recruitment and retention rates (34).  Percentage of participants that complete baseline questionnaire and baseline confidence and behaviour surveys (34).  Ability to randomise 30 participants in a 3-month recruitment window (35).  Percentage of participants that commence their allocated within 14 days (34) |
| Feasibility of randomisation procedures | REDCap database | T-test for comparison of baseline characteristics of intervention and control groups.  Open ended survey question about awareness of intervention (control group only) |
| Acceptability and suitability of intervention materials. | Focus group/Interview data | Researcher led semi-structured interviews using theoretical framework of acceptability (33)  Percentage of participants that complete their allocated treatment within the 12 week intervention period (34). |

# STATISTICAL ANALYSIS PLAN

Phase 1- Pilot study

We intend to recruit a sample size of 30 participants for this pilot study. This is a pragmatic estimation based on the expected sample size of 278 participants that would be needed for a future definitive study that would give 80% power to detect a mean difference of 0.25kg of interdialytic weight gain between the intervention and control groups (36).

Data analysis will be carried out by researchers from the School of Public Health at the University of Sydney who will be blinded to participant allocation to intervention and usual care arms (control group).

Quantitative data analysis

Descriptive statistics will be used to summarise quantitative data collected for the pilot study, including baseline demographic data, weight, pre-dialysis blood pressure and participant responses from the surveys measuring behaviours that participants engaged in to manage their fluids and how confidence for engaging in strategies for managing their fluid intake (37). Descriptive statistics will be used as there will not be sufficient data to compare overall differences between the intervention and control groups.

Qualitative data analysis

The Framework Analysis model (38) will be used to summarise transcripts from the semi-structured interviews adopted to measure the acceptability of the intervention materials and the feasibility of the randomization procedures.

Phase 2- Definitive trial

We intend to recruit a sample size of 278 participants for this study to give us 80% power to detect a difference of 0.25kg of interdialytic weight gain between the intervention and control groups. The sample size has been determined using the G\*Power application (39), based on the pooled results from a systematic review by Bossola et al (40) that investigated the role of educational, cognitive, behavioural or psychological interventions in reducing interdialytic weight gain amongst patients receiving haemodialysis treatment for chronic kidney disease.

Data analysis will be carried out by researchers from the School of Public Health at the University of Sydney who will be blinded to participant allocation to intervention and usual care arms (control group). control groups.

An intention to treat analysis will be used to compare primary and secondary outcomes between the intervention and control groups. Descriptive statistics will be used to summarise baseline demographic data and to compare participant responses in the follow-up surveys measuring behaviours that participants engaged in to manage their fluids and how confidence for engaging in strategies for managing their fluid intake (37). Independent sample t-tests will be used to assess changes in pre- and post-intervention interdialytic weight gain and pre-dialysis systolic blood pressure. Linear regression models will be used to compare the overall difference in interdialytic weight gain between intervention and control groups, adjusting for dialysis treatment location, baseline weight, gender, age, postcode, and ethnicity.

# DATA GOVERNANCE

7.1DATA STORAGE, ACCESS AND SECURITY

All data collected for this research project will be submitted anonymously or have personal identifying information removed. Dialysis nurses at each site will access participant data in clinical databases and will extract data for researchers that is needed for analysis (weight and pre-dialysis systolic blood pressure measurements). Under no circumstances will researchers have direct access to NBMLHD clinical databases or patient records. Individual’s will not be able to be identified or be re-identifiable.

All data will be stored securely using University of Sydney REDCap database. Each record will be given a unique identifier. All data will be stored on password protected databases, with no identifiable information being including in the main dataset. Study data will be stored for 5 years in accordance with University of Sydney’s policy on retention of study data. All paper forms of data will be destroyed after data is entered into the University of Sydney’s secure online database.

7.2 USE AND DISCLOSURE

All data will be held securely on the REDCap database with password protection and access restricted to the study team. The findings from the study will be presented in an aggregated form. Individual’s will not be identifiable in any publication or presentation.

7.3 DATA RETENTION AND DISPOSAL

As per the General Retention and Disposal Authority document (GDA 17) requirements, based on section 21 (2) (c) of the State Records Act 1998 (NSW) last updated 2019 requirements and The Australian Code for the Responsible Conduct of Research for information on retention of research data, the data will be kept for the required minimum 5 years post study closure. After 5 years the data will then be deleted from the REDCap database in accordance with the NBMLDH Research Data Management Procedure. All paper forms of data will be destroyed after data is entered into the University of Sydney’s secure online database.

* 1. FUTURE USE OF DATA

Data collected in this study is not intended to be used in future studies.

7.5 RESEARCHDATA MANAGEMENT PLAN (RDMP)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Funding** | **Confirmed or Sought?** | | | **Amount of funding $** |
| **Researchers’ department or organisation** | Confirmed | Sought | Not Sought |  |
| **External Competitive Grant** | Confirmed | Sought | Not Sought |  |
| **Internal competitive grant** | Confirmed | Sought | Not Sought |  |
| **Sponsor** | Confirmed | Sought | Not Sought |  |

# PUBLICATION & DISSEMINATION

Participants who provide an email address in their consent form will be informed of the study findings at the conclusion of the study. Participants will have the choice to download a copy of their responses for all surveys completed in REDCap.

The results of this research project will be presented as a peer-reviewed manuscript and presented at national and international conferences.

# APPENDICES

* 1. *VHS*
  2. *Information about fluids*
  3. *Master e-demographic survey*
  4. *Master flyer*
  5. *Master PICF with provision for Site PICF*
  6. *Master e-PIS*
  7. *Master e-consent form*
  8. *Master withdrawal of consent with permission for site withdrawal*
  9. *Master e-withdrawal of consent with permission for site withdrawal*
  10. *IDWG survey*
  11. *Pre-dialysis sBP survey*
  12. *Behaviour survey*
  13. *Confidence survey*
  14. *Acceptability questionnaire*
  15. *Feasibility of randomisation questionnaire*

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