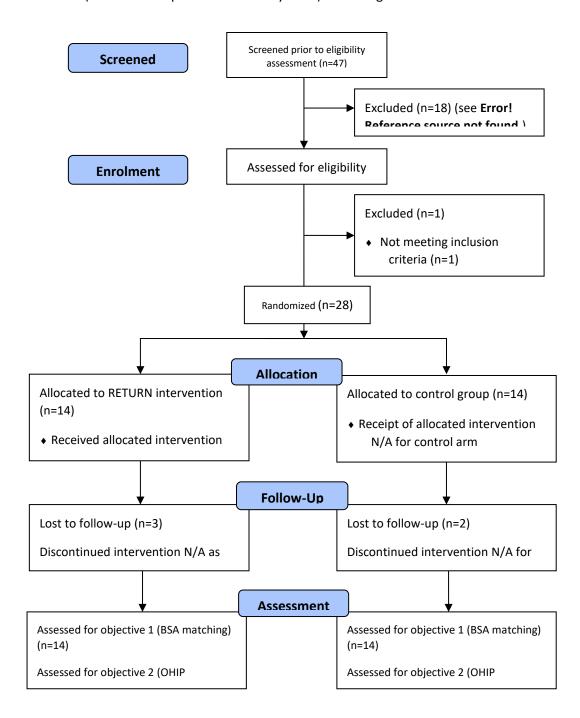
ISRCTN Basic Results Summary

Participant Flow

CONSORT 2010 (extension for pilot and feasibility trials) Flow Diagram



Baseline Characteristics

Table Error! No text of specified style in document.-1 Baseline demographic details and clinical findings

| Demographic | summary | RETURN Intervention | Standard Care | Overall |
|---------------------|---|---------------------|---------------------|---------------------|
| Gender, n(%) | N | 14 | 14 | 28 |
| | Female | 8 (57.1%) | 6 (42.9%) | 14 (50.0%) |
| | Male | 6 (42.9%) | 8 (57.1%) | 14 (50.0%) |
| Age (years) Summary | n (n missing) | 14 (0) | 14 (0) | 28 (0) |
| | Mean (S.D.) | 33.1 (9.9) | 35.7 (11.6) | 34.4 (10.7) |
| | Median (Q1-Q3) | 34.9 (24.9 to 43.0) | 33.1 (28.7 to 45.3) | 34.9 (25.4 to 43.5) |
| | Min-Max | 18.7 to 46.7 | 19.2 to 57.5 | 18.7 to 57.5 |
| Ethnicity, n(%) | N | 14 | 14 | 28 |
| | Asian or Asian British: Indian | 1 (7.1%) | 1 (7.1%) | 2 (7.1%) |
| | Asian or Asian British: Pakistani | 1 (7.1%) | 0 (0.0%) | 1 (3.6%) |
| | Mixed/ multiple ethnic groups: Any other Mixed/Multiple ethnic background | 0 (0.0%) | 1 (7.1%) | 1 (3.6%) |
| | Mixed/ multiple ethnic groups: White and Black African | 0 (0.0%) | 1 (7.1%) | 1 (3.6%) |
| | White: Any other white background | 1 (7.1%) | 0 (0.0%) | 1 (3.6%) |
| | White: English/Welsh/Scottish/Northern Irish/British | 11 (78.6%) | 11 (78.6%) | 22 (78.6%) |

| Demographic | summary | RETURN Intervention | Standard Care | Overall |
|-----------------------------|---|---------------------|---------------|------------|
| Highest qualification, n(%) | N | 14 | 14 | 28 |
| | No formal qualifications | 2 (14.3%) | 4 (28.6%) | 6 (21.4%) |
| | GCSEs / O Levels (any grade), NVQ Level 1 or similar | 5 (35.7%) | 4 (28.6%) | 9 (32.1%) |
| | 2+ A Levels/NVQ Level 3 or similar | 4 (28.6%) | 3 (21.4%) | 7 (25.0%) |
| | Undergraduate degree (BA, BSc etc.) | 0 (0.0%) | 1 (7.1%) | 1 (3.6%) |
| | Postgraduate degree or similar (PGCE, MA, PhD etc.) | 3 (21.4%) | 2 (14.3%) | 5 (17.9%) |
| Employment Status, n(%) | N | 14 | 14 | 28 |
| | Employed or self employed full-time (30 hours or more/week) | 6 (42.9%) | 2 (14.3%) | 8 (28.6%) |
| | Employed or self employed part - time (Less than 30 hours/week) | 2 (14.3%) | 2 (14.3%) | 4 (14.3%) |
| | Reason for not working provided | 6 (42.9%) | 9 (64.3%) | 15 (53.6%) |
| | Data unobtainable | 0 (0.0%) | 1 (7.1%) | 1 (3.6%) |
| Reasons for not working, | N | 6 | 9 | 15 |
| n(%) ¹ | Currently looking for paid work | 2 (33.3%) | 1 (11.1%) | 3 (20.0%) |
| | Not currently looking for paid work (e.g. Looking after family) | 0 (0.0%) | 1 (11.1%) | 1 (6.7%) |
| | Student | 3 (50.0%) | 2 (22.2%) | 5 (33.3%) |
| | Unable to work Due to disability | 1 (16.7%) | 4 (44.4%) | 5 (33.3%) |
| | Other ² | 0 (0.0%) | 1 (11.1%) | 1 (6.7%) |
| Receipt of benefits, n(%) | N | 14 | 14 | 28 |
| | No | 10 (71.4%) | 4 (28.6%) | 14 (50.0%) |
| | Yes | 4 (28.6%) | 9 (64.3%) | 13 (46.4%) |
| | Data unobtainable | 0 (0.0%) | 1 (7.1%) | 1 (3.6%) |

 $^{\rm 1}$ Denominator for percentage is those that have provided reason for not working $^{\rm 2}$ Other reason provided: unemployed

| Demographic | summary | RETURN Intervention | Standard Care | Overall |
|-----------------------------|---|---------------------|---------------|-----------------|
| Infection at baseline, n(%) | N | 14 | 14 | 28 |
| | No | 8 (57.1%) | 4 (28.6%) | 12 (42.9%) |
| | Yes | 6 (42.9%) | 10 (71.4%) | 16 (57.1%) |
| Clinical treatments | N | 14 | 14 | 28 |
| provided: n [n events] (%) | Radiographs | 7 [7] (50%) | 9 [9] (64.3%) | 16 [16] (57.1%) |
| | Assessment and advice about presenting complaint | 12 (85.7%) | 10 (71.4%) | 22 (78.6%) |
| | Extraction | 1 [3] (7.1%) | 5 [5] (35.7%) | 6 [8] (21.4%) |
| | Prescription for antibiotics | 4 (28.6%) | 5 (35.7%) | 9 (32.1%) |
| | Treatment of dental trauma ³ including splints | 1 [1] (7.1%) | 0 | 1 [1] (3.6%) |
| | Endodontic treatment of permanent teeth ⁴ | 1 [1] (7.1%) | 2 [2] (14.3%) | 3 [3] (10.7%) |
| | Temporary filling or dressing | 4 [4] (28.6%) | 1 [1] (7.1%) | 5 [5] (17.9%) |
| | Permanent filling ⁵ | 0 | 1 [1] (7.1%) | 1 [1] (3.6%) |
| | Other ⁶ | 4 (28.6%) | 0 | 4 (14.3%) |

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³ e.g. avulsion, subluxation, lateral luxation, intrusion, concussion, fractured tooth, alveolar fracture

⁴ including pulpal extirpation only

⁵ provision of amalgam, composite resin, compomer, glass ionomer, silicate, silicophosphate, marginal correction/ adjustment/ repair ⁶ Other treatment provided in the RETURN intervention arm were: 1 x Suture, 2 x Acute Mucosal Infection Treatment, 1 x Eased high spots, occlusion checked

Primary Objectives and Measures

1.1 Outcome data

1.1.1 Primary outcome assessments

1.1.1.1 Primary efficacy assessment 1 – BSA data matching

For urgent care appointments where a match was expected 22 unique records were found. Out of these records, 1 of the records did not have a treatment completion date that matched the date of the urgent care appoint (when the participant was randomised into the study) the record found fell before randomisation, but still during the overall study period. Urgent care appointment data was expected from 26/28 recruited participants, 2 participants were randomised at the dental hospital, where it would not be expected that an urgent treatment record would be obtainable within the BSA data. Therefore, the gives an overall matching rate of 22/26 = 84.6% for fully or partially matched records or 21/26 = 80.8% fully matched.

Additionally, 1 study ID number returned multiple records based on the participants identifiers, this participant is therefore not included in the in the above as a successful match. Also, for 1 further study ID randomised in the dental hospital, 1 urgent care record was found but with a treatment completion date not on the same date as the urgent care appointment when they were randomised. This participant is not included in the above matching rate as participants from this site were not expected to find a match for urgent care visits. Overall data was returned for 23/28 (82.1%).

For non-urgent dental attendance, 3 records were found in the BSA data, all 3 of which also had a fully matched urgent treatment record.

For the main trial the accuracy of the matching should be improved by providing NHS BSA with additional identifiers including post code, checking the spelling of names and checking of dates of birth.

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1.1.1.2 Primary efficacy assessment 2 – OHIP 14 data

Table Error! No text of specified style in document.-2 OHIP-14 results

| Details | summary | RETURN | Standard | Overall |
|-----------------------------------|----------------|---------------------|---------------------|---------------------|
| | | Intervention | Care | |
| Baseline OHIP-14 score Summary | n (n missing) | 14 (0) | 13 (1) | 27 (1) |
| | Mean (S.D.) | 23.3 (15.8) | 22.7 (13.3) | 23.0 (14.4) |
| | Median (Q1-Q3) | 23.5 (10.0 to 35.2) | 17.2 (14.0 to 30.0) | 18.0 (11.0 to 35.2) |
| | Min-Max | 0.0 to 50.0 | 5.0 to 46.0 | 0.0 to 50.0 |
| Follow-up OHIP-14 score | n (n missing) | 11 (3) | 12 (2) | 23 (5) |
| Summary | Mean (S.D.) | 15.5 (13.3) | 18.8 (14.0) | 17.2 (13.4) |
| | Median (Q1-Q3) | 10.0 (8.0 to 22.0) | 19.5 (5.5 to 30.5) | 13.0 (8.0 to 27.0) |
| | Min-Max | 0.0 to 47.0 | 2.0 to 43.0 | 0.0 to 47.0 |
| Change in OHIP-14 scores | n (n missing) | 11 (3) | 11 (3) | 22 (6) |
| Summary (follow up - baseline) | Mean (S.D.) | -7.7 (17.2) | -4.5 (12.2) | -6.1 (14.6) |
| | Median (Q1-Q3) | -1.0 (-16.0 to 4.0) | -3.0 (-7.0 to 4.0) | -3.0 (-11.0 to 4.0) |
| | Min-Max | -42.0 to 12.0 | -35.0 to 9.8 | -42.0 to 12.0 |

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1.1.1.3 Primary efficacy assessment 3 – Recruitment rates

In total 28 patients were randomised across 3 sites. 2 (7.1%) at the dental hospital, 20 (71.4%) at in hours emergency dental practice and 6 (21.4%) at the out of hours emergency dental practice.

1.1.1.4 Primary efficacy assessment 2 – Fidelity to intervention

The number of patients reported to have engaged with at least some of the intervention was 14/14 (100%) patients randomised to intervention.

1.1.2 Secondary outcome assessments

1.1.2.1 Secondary efficacy assessment 1 – BSA data vs CRF data

In this section the first and second table compare the treatments received at the initial urgent care appointment. In the first table the BSA reported treatment fields are compared to the baseline CRF data collection (completed at baseline by the dental team at site) and the second table compares BSA reported treatments fields against the follow up CRF data (but for items relating to the baseline visit) which is reported by the participants.

The third table compares all dental treatments received in the 4 months prior to follow up (including urgent care appointment at baseline). To compare this, all urgent and routine records found in the BSA data will be combined and compared to the treatments reported on follow up CRF data, the items for the previous 4 months visits are collected separately from questions at follow up that relate to baseline.

Note that for the baseline comparisons (first and second table) only records from sites in the BSA records that are expected to be returned are included (i.e. the 22 participants as described in section 1.1.1.1).

Table Error! No text of specified style in document.-3 Baseline BSA vs Baseline CRF

| BSA Dental Treatment Field | Number reported in BSA | Number reported in CRF data | Number matched | Number part match (reported the same treatment but not the same frequency) | Number not matched |
|--------------------------------|------------------------|-----------------------------|----------------|---|--------------------|
| Scale and Polish * | 0 | (not reported) | N/A | N/A | N/A |
| Fluoride Varnish * | 0 | 0 | 22 | 0 | 0 |
| Fissure Sealants | 0 | (not reported) | N/A | N/A | N/A |
| Radiograph | 0 | 12 | 10 | 0 | 12 |
| Endodontic Treatment | 0 | 3 | 19 | 0 | 3 |
| Permanent Fillings | 2 | 1 | 21 | 0 | 1 |
| Extractions | 0 | 2 | 20 | 0 | 2 |
| Crowns Provided | 0 | 0 | 22 | 0 | 0 |
| Upper Denture Acrylic | | | | | |
| Lower Denture Acrylic | | | | | |
| Upper Denture Metal | | | | | |
| Lower Denture Metal | | | | | |
| Veneers Applied ** | | | | | |
| Inlays | | | | | |
| Bridges Fitted | | | | | |
| Referral For Advanced | 0 | (not reported) | N/A | N/A | N/A |
| Mandatory Services | | | | | |
| Examination | 0 | 17 | 5 | 0 | 17 |
| Antibiotic Items Prescribed | 2 | 6 | 16 | 0 | 6 |
| Other Treatment | 21 | 1 | 2 | 0 | 20 |
| Domiciliary Visits | 0 | (not reported) | N/A | N/A | N/A |
| Sedation | 0 | (not reported) | N/A | N/A | N/A |

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^{*} Items marked with an Asterix can only be considered partly matched.

^{**} Item not returned in BSA data.

Out of the 22 participants described in section 1.1.1.1, with fully matched and expected urgent care appointments in the BSA, 18 were successfully followed-up, therefore the following table is based on data matched for 18 participants.

Table Error! No text of specified style in document.-4 Baseline BSA Vs follow-up data relating to baseline

| BSA Dental Treatment Field | Number reported in BSA | Number reported in CRF data | Number matched | Number part match (reported the same treatment but not the same frequency) | Number not matched |
|--------------------------------|------------------------|-----------------------------|----------------|---|-----------------------|
| Scale and Polish * | 0 | (not reported) | N/A | N/A | N/A |
| Fluoride Varnish * | 0 | 0 | 18 | 0 | 0 |
| Fissure Sealants | 18 | (not reported) | N/A | N/A | N/A |
| Radiograph | 0 | 9 (8 participants) | 10 | 0 | 8 |
| Endodontic Treatment | 0 | 2 | 16 | 0 | 2 |
| Permanent Fillings | 1 | 0 | 17 | 0 | 1 |
| Extractions | 0 | 0 | 18 | 0 | 0 |
| Crowns Provided | 0 | 0 | 18 | 0 | 0 |
| Upper Denture Acrylic | | | | | |
| Lower Denture Acrylic | | | | | |
| Upper Denture Metal | | | | | |
| Lower Denture Metal | | | | | |
| Veneers Applied ** | | | | | |
| Inlays | | | | | |
| Bridges Fitted | | | | | |
| Referral For Advanced | 18 | (not reported) | N/A | N/A | N/A |
| Mandatory Services | | | | | |
| Examination | 0 | 5 | 13 | 0 | 5 |
| Antibiotic Items Prescribed | 2 | 6 | 12 | 0 | 6 |
| Other Treatment | 18 | (not reported) | N/A | N/A | N/A |

| Domiciliary Visits | 0 | (not reported) | N/A | N/A | N/A |
|--------------------|---|----------------|-----|-----|-----|
| Sedation | 0 | (not reported) | N/A | N/A | N/A |

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The following table describes data from all dental visits in the 4 months prior to follow up at 4 months (including urgent care appointments) and therefore included in these summaries are all participants for where BSA data was returned, in this case 23 unique participants data was retrieved from the BSA data however out of these only 19 were successfully followed up.

Table Error! No text of specified style in document.-5 All BSA Vs follow up data for all dental visits

| BSA Dental Treatment Field | Number reported in BSA | Number reported in CRF data | Number matched | Number part match (reported the same treatment but not the same frequency) | Number not matched |
|-------------------------------|------------------------|-----------------------------|----------------|---|--------------------|
| Scale and Polish * | 1 | 0 | 18 | 0 | 1 |
| Fluoride Varnish * | 0 | 0 | 19 | 0 | 0 |
| Fissure Sealants | 0 | (not reported) | N/A | N/A | N/A |
| Radiograph | 4 (2 participants) | 9 (7 participants) | 11 | 1 | 7 |
| Endodontic Treatment | 0 | 2 | 17 | 0 | 2 |
| Permanent Fillings | 1 | 0 | 18 | 0 | 1 |
| Extractions | 1 | 7 (2 participants) | 15 | 0 | 4 |
| Crowns Provided | 0 | 0 | 19 | 0 | |
| Upper Denture Acrylic | | | | | |
| Lower Denture Acrylic | | | | | |
| Upper Denture Metal | | | | | |
| Lower Denture Metal | | | | | |
| Veneers Applied ** | | | | | |
| Inlays | | | | | |
| Bridges Fitted | | | | | |

^{*}Items marked with an Asterix can only be considered partly matched.

^{**} Item not returned in BSA data.

| Referral For Advanced | 0 | 2 | 17 | 0 | 2 |
|-----------------------|----|----------------|-----|-----|-----|
| Mandatory Services | | | | | |
| Examination | 2 | 5 | 14 | 0 | 5 |
| Antibiotic Items | 2 | 4 | 15 | 0 | 5 |
| Prescribed | | | | | |
| Other Treatment | 19 | (not reported) | N/A | N/A | N/A |
| Domiciliary Visits | 0 | (not reported) | N/A | N/A | N/A |
| Sedation | 0 | (not reported) | N/A | N/A | N/A |

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1.1.2.2 Secondary efficacy assessment 2 – MDAS

Table Error! No text of specified style in document.-6 MDAS results

| Details | summary | RETURN Intervention | Standard Care | Overall |
|---|----------------|------------------------|---------------------|--------------------|
| Baseline MDAS (pre-intervention) Summary | n (n missing) | 14 (0) | 13 (1) | 27 (1) |
| | Mean (S.D.) | 14.2 (7.8) | 13.9 (5.4) | 14.1 (6.6) |
| | Median (Q1-Q3) | 9.0 (9.0 to 22.0) | 12.0 (10.0 to 20.0) | 11.0 (9.0 to 20.0) |
| | Min-Max | 5.0 to 25.0 | 6.0 to 21.0 | 5.0 to 25.0 |
| Baseline MDAS (post-intervention) Summary | n (n missing) | 13 (1) | - | - |
| | Mean (S.D.) | 12.4 (7.4) | - | - |
| | Median (Q1-Q3) | 9.0 (7.0 to 17.0) | - | - |
| | Min-Max | 5.0 to 25.0 | - | - |
| 4-month MDAS Summary | n (n missing) | 11 (3) | 12 (2) | 23 (5) |
| | Mean (S.D.) | 12.5 (5.9) | 14.1 (5.0) | 13.3 (5.4) |
| | Median (Q1-Q3) | 9.0 (9.0 to 19.0) | 15.0 (10.0 to 18.5) | 13.0 (9.0 to 19.0) |
| | Min-Max | 5.0 to 22.0 | 6.0 to 22.0 | 5.0 to 22.0 |
| MDAS change from baseline Summary | n (n missing) | 10 (4) | 12 (2) | 22 (6) |
| | Mean (S.D.) | 0.5 (3.2) | -0.1 (5.7) | 0.2 (4.6) |
| | Median (Q1-Q3) | 0.0 (0.0 to 2.0) | 0.5 (-4.5 to 3.0) | 0.0 (-1.0 to 2.0) |

^{*}Items marked with an Asterix can only be considered partly matched.

^{**} Item not returned in BSA data.

| | Min-Max | -6.0 to 6.0 | -10.3 to 10.0 | -10.3 to 10.0 |
|--|----------------|-------------------|---------------|---------------|
| MDAS change from, pre to post-intervention | n (n missing) | 13 (1) | - | - |
| Summary | Mean (S.D.) | -1.0 (3.5) | - | - |
| | Median (Q1-Q3) | 0.0 (-1.0 to 0.0) | - | - |
| | Min-Max | -12.0 to 3.0 | - | - |

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Table Error! No text of specified style in document.-7 MDAS anxiety levels

| Details | Level* | RETURN | Standard | Overall |
|-------------------------------------|---------------------------------|--------------|-----------|------------|
| | | Intervention | Care | |
| Baseline MDAS anxiety levels (pre- | N | 14 | 14 | 28 |
| intervention), n(%) | 1. Low dental anxiety | 8 (57.1%) | 5 (35.7%) | 13 (46.4%) |
| | 2. Moderate/High dental anxiety | 1 (7.1%) | 4 (28.6%) | 5 (17.9%) |
| | 3. Very high dental anxiety | 5 (35.7%) | 4 (28.6%) | 9 (32.1%) |
| | Missing MDAS | 0 (0.0%) | 1 (7.1%) | 1 (3.6%) |
| Baseline MDAS anxiety levels (post- | N | 14 | - | - |
| intervention), n(%) | 1. Low dental anxiety | 9 (64.3%) | - | - |
| | 2. Moderate/High dental anxiety | 1 (7.1%) | - | - |
| | 3. Very high dental anxiety | 3 (21.4%) | - | - |
| | Missing MDAS | 1 (7.1%) | - | - |
| Follow-up MDAS anxiety levels, n(%) | N | 14 | 14 | 28 |
| | 1. Low dental anxiety | 6 (42.9%) | 3 (21.4%) | 9 (32.1%) |
| | 2. Moderate/High dental anxiety | 2 (14.3%) | 6 (42.9%) | 8 (28.6%) |
| | 3. Very high dental anxiety | 3 (21.4%) | 3 (21.4%) | 6 (21.4%) |
| | Missing MDAS | 3 (21.4%) | 2 (14.3%) | 5 (17.9%) |

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^{*}Level: 5 ≤ MDAS ≤ 10 = low, 10 < MDAS < 19 = Moderate/ High. MDAS ≥ 19 = very high.

1.1.2.3 Secondary efficacy assessment 3 – protection motivation theory

Table Error! No text of specified style in document.-8 PMT completeness

| Timepoint | No. of completed items | RETURN | Standard | Overall |
|------------------------------------|---------------------------------|--------------|------------|------------|
| | | Intervention | Care | |
| Baseline number of completed items | N | 14 | 14 | 28 |
| (pre-intervention), n(%) | 9 Items completed | 0 (0.0%) | 1 (7.1%) | 1 (3.6%) |
| | 10 Items completed | 14 (100.0%) | 12 (85.7%) | 26 (92.9%) |
| | PMT questionnaire not completed | 0 (0.0%) | 1 (7.1%) | 1 (3.6%) |
| Baseline number of completed items | N | 14 | - | - |
| (post-intervention), n(%) | 10 Items completed | 13 (92.9%) | - | - |
| | PMT questionnaire not completed | 1 (7.1%) | - | - |
| Follow-up number of completed | N | 14 | 14 | 28 |
| items, n(%) | 10 Items completed | 11 (78.6%) | 12 (85.7%) | 23 (82.1%) |
| | PMT questionnaire not completed | 3 (21.4%) | 2 (14.3%) | 5 (17.9%) |

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Only 1 returned questionnaire was not fully completed for this outcome. This was a participant in the Standard care arm at baseline and the item missing was question 5: "I intend to visit a dentist for a planned appointment (not with a problem)".

1.1.2.4 Secondary efficacy assessment 4 – Halitosis & bad breath

Table Error! No text of specified style in document.-9 Details of Halitosis and bad breath questionnaire

| Question | Answer | RETURN | Standard | Overall |
|--|---------------------|--------------|------------|------------|
| | | Intervention | Care | |
| Baseline: Have you ever noticed a bad taste | N | 14 | 14 | 28 |
| in your mouth?, n(%) | No | 6 (42.9%) | 3 (21.4%) | 9 (32.1%) |
| | Yes | 8 (57.1%) | 10 (71.4%) | 18 (64.3%) |
| | Missing | 0 (0.0%) | 1 (7.1%) | 1 (3.6%) |
| Baseline: If you told us you have ever | N | 8 | 10 | 18 |
| noticed a bad taste how much does it bother you?, n(%) | Not at all bothered | 0 (0.0%) | 1 (10.0%) | 1 (5.6%) |
| | Not very bothered | 4 (50.0%) | 3 (30.0%) | 7 (38.9%) |
| | Very bothered | 1 (12.5%) | 3 (30.0%) | 4 (22.2%) |
| | Extremely bothered | 3 (37.5%) | 3 (30.0%) | 6 (33.3%) |
| Baseline: Have you ever noticed you have | N | 14 | 14 | 28 |
| bad breath?, n(%) | No | 4 (28.6%) | 5 (35.7%) | 9 (32.1%) |
| | Yes | 10 (71.4%) | 8 (57.1%) | 18 (64.3%) |
| | Missing | 0 (0.0%) | 1 (7.1%) | 1 (3.6%) |
| Baseline: If you told us that you have ever | N | 10 | 8 | 18 |
| noticed bad breath how much does it bother | Not very bothered | 1 (10.0%) | 0 (0.0%) | 1 (5.6%) |
| you?, n(%) | Very bothered | 1 (10.0%) | 5 (62.5%) | 6 (33.3%) |
| | Extremely bothered | 8 (80.0%) | 3 (37.5%) | 11 (61.1%) |
| Follow-up: Have you ever noticed a bad | N | 14 | 14 | 28 |
| taste in your mouth?, n(%) | No | 7 (50.0%) | 7 (50.0%) | 14 (50.0%) |
| | Yes | 2 (14.3%) | 3 (21.4%) | 5 (17.9%) |
| | Missing | 5 (35.7%) | 4 (28.6%) | 9 (32.1%) |

| Follow-up: If you told us you have ever | N | 2 | 3 | 5 |
|--|---------------------|------------|-----------|------------|
| noticed a bad taste how much does it bother | Not at all bothered | 1 (50.0%) | 0 (0.0%) | 1 (20.0%) |
| you?, n(%) | Very bothered | 0 (0.0%) | 1 (33.3%) | 1 (20.0%) |
| | Extremely bothered | 1 (50.0%) | 2 (66.7%) | 3 (60.0%) |
| Follow-up: Have you ever noticed you have | N | 14 | 14 | 28 |
| bad breath?, n(%) | No | 8 (57.1%) | 5 (35.7%) | 13 (46.4%) |
| | Yes | 1 (7.1%) | 5 (35.7%) | 6 (21.4%) |
| | Missing | 5 (35.7%) | 4 (28.6%) | 9 (32.1%) |
| Follow-up: If you told us that you have ever | N | 1 | 5 | 6 |
| noticed bad breath how much does it bother | Extremely bothered | 1 (100.0%) | 3 (60.0%) | 4 (66.7%) |
| you?, n(%) | Not very bothered | 0 (0.0%) | 1 (20.0%) | 1 (16.7%) |
| | Very bothered | 0 (0.0%) | 1 (20.0%) | 1 (16.7%) |

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Table Error! No text of specified style in document.-10 Baseline infection vs baseline bad taste reported

| | Bad t | taste reported | | |
|--------------------|-------|----------------|-------|--|
| Baseline infection | No | Yes | Total | |
| No | 6 | 6 | 12 | |
| Yes | 3 | 12 | 15 | |
| Total | 9 | 18 | 27 | |

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Table Error! No text of specified style in document.-11 Baseline infection vs baseline bad breath reported

| | Bad breath reported | | | |
|--------------------|---------------------|----|----|--|
| Baseline infection | No Yes Tota | | | |
| No | 6 | 6 | 12 | |
| Yes | 3 | 12 | 15 | |
| Total | 9 | 18 | 27 | |

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1.1.2.5 Secondary efficacy assessment 5 – Health economic outcome completion

Table Error! No text of specified style in document.-12 EQ5D completeness of data

| Timepoint | No. of completed items | RETURN | Standard | Overall |
|-------------------------------|----------------------------------|--------------|------------|------------|
| | | Intervention | Care | |
| Baseline number of completed | N | 14 | 14 | 28 |
| items, n(%) | 5 Items completed | 1 (7.1%) | 0 (0.0%) | 1 (3.6%) |
| | 6 Items completed | 12 (85.7%) | 12 (85.7%) | 24 (85.7%) |
| | EQ5D questionnaire not completed | 1 (7.1%) | 2 (14.3%) | 3 (10.7%) |
| Follow-up number of completed | N | 14 | 14 | 28 |
| items, n(%) | 6 Items completed | 11 (78.6%) | 12 (85.7%) | 23 (82.1%) |
| | EQ5D questionnaire not completed | 3 (21.4%) | 2 (14.3%) | 5 (17.9%) |

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Only 1 returned questionnaire was not fully completed for this outcome. This was a participant in the RETURN intervention arm at baseline and the item missing was item 3: "USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)".

The following table summarises the completeness of data for the resource use questionnaire completed at follow up. As some items are not always applicable to every participant, for example, the treatments received at past dental visits or medicines prescribed or purchased for dental problems, only questions where an answer should be provided by all participants are covered in the table below to give an idea of the completion rates.

To put the completion of the items into context, 23/28 (82.1%) patients were successfully followed up, 11/14 (78.6%) of which were in the REUTRN intervention arm and 12/14 (85.7%) of which were in the control arm. All participants successfully followed-up completed at least part of the resource use questionnaire.

Table Error! No text of specified style in document.-13 Resource use questionnaire data completion

| · · · · · · · · · · · · · · · · · · · | Yes No | (n=11) 3 | (n=12) | (n=23) |
|---|--|-------------|--------|--------|
| · · · · · · · · · · · · · · · · · · · | No | | 3 | |
| emergency) in the last four months. | | | _ | 6 |
| | | 8 | 9 | 17 |
| | Missing | 0 | 0 | 0 |
| 1b) How many times have you visited? | Value provided | 3 | 3 | 6 |
| (Must answer yes to 1a, N/A is those that answered no) | N/A | 8 | 9 | 17 |
| | Missing | 0 | 0 | 0 |
| | At least 1 type of dentist selected | 3 | 3 | 6 |
| (Must answer yes to 1a, N/A is those that answered no) | N/A | 8 | 9 | 17 |
| | Missing | 0 | 0 | 0 |
| 1d) If you visited an NHS dentist, did you pay for treatment? | Yes | 3 | 2 | 5 |
| (Must answer yes to 1a, N/A is those that answered no) | No | 0 | 1 | 1 |
| | N/A | 8 | 9 | 17 |
| | Missing | 0 | 0 | 0 |
| 2a) Have you visited a dentist for an urgent appointment in the | Yes | 5 | 2 | 7 |
| | No | 6 | 10 | 16 |
| you agreed to take part in the study)? | Missing | 0 | 0 | 0 |
| , , , , , | At least one of in hours or out of hours | 5 | 2 | 7 |
| out-of-hours urgent appointment(s)? | N/A | 6 | 10 | 16 |
| (Must answer yes to 2a, N/A is those that answered no) | Missing | 0 | 0 | 0 |

| Question | Answer | RETURN Intervention (n=11) | Standard Care (n=12) | Overall (n=23) |
|---|----------------------------|----------------------------------|----------------------------|----------------|
| 2c) If you have attended an urgent appointment in the last 4 | At least 1 type of dentist | 5 | 2 | 7 |
| months, did you visit an NHS dentist, private dentist or Dental | selected | | | |
| Hospital emergency clinic? | N/A | 6 | 10 | 16 |
| (Must answer yes to 2a, N/A is those that answered no) | Missing | 0 | 0 | 0 |
| 2d) If you visited an NHS dentist for urgent appointment(s) in the | Yes | 2 | 0 | 2 |
| last four months, did you pay for your | No | 2 | 1 | 3 |
| treatment? | N/A | 6 | 10 | 16 |
| (Must answer yes to 2a, N/A is those that answered no) | Missing | 1 | 1 | 2 |
| Section 4: How many times have you seen a GP at a GP surgery or | Value entered | 10 | 11 | 21 |
| at your home, or spoken to a GP by telephone due to problems with your teeth, mouth or dentures in the last 4 months | Missing | 1 | 1 | 2 |
| Section 4: How many times have you seen a nurse at a GP | Value entered | 10 | 11 | 21 |
| surgery, at your home, or in any other location in the community due to problems with your teeth, mouth or dentures in the last four months? This may include GP practice nurses, health visitors district nurses and midwives etc. | Missing | 1 | 1 | 2 |
| Section 4: How many nights have you been in hospital overnight | Value entered | 10 | 11 | 21 |
| due to problems with your teeth, mouth or dentures in the last four months? | Missing | 1 | 1 | 2 |
| Section 4: How many times have you been in hospital A&E due to | Value entered | 10 | 11 | 21 |
| problems with your teeth, mouth or dentures in the last four months? | Missing | 1 | 1 | 2 |
| Section 4: How many times have you been to a hospital clinic due | Value entered | 10 | 12 | 22 |
| to problems with your teeth, mouth or dentures in the last four months? | Missing | 1 | 0 | 1 |
| 7) How much do you think you have spent on travel as a result of | Value entered | 4 | 4 | 8 |
| attending the dentist, doctor or hospital due to problems with your teeth, mouth or dentures in the last four months (since your | Missing | 7 | 8 | 15 |

| Question | Answer | RETURN Intervention (n=11) | Standard Care (n=12) | Overall (n=23) |
|--|---------------|----------------------------------|----------------------------|----------------|
| urgent dental appointment when you agreed to take part in this study)? | | | | |
| 8) Did you have to pay any other expenses (money) in the last four months (since your urgent dental appointment when you agreed to take part in the study) due to problems with your teeth, mouth or dentures? | Yes | 1 | 0 | 1 |
| | No | 10 | 12 | 22 |
| | Missing | 0 | 0 | 0 |
| 10a) If you are in paid work please tell us the number of days you | Value entered | 2 | 2 | 4 |
| have been away from work in the last four months (since your | N/A | 6 | 8 | 14 |
| urgent dental appointment when you agreed to take part in this study) due to problems with your teeth, mouth or dentures or N/A selected | Missing | 3 | 2 | 5 |

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Adverse Events

There were no adverse events associated with this trial.